IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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IN RE: TYLENOL (ACETAMINOPHEN) MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	:	2:13-md-02436-LS
	:	PHILADELPHIA, PA
	:	April 27, 2016
	:	10:11 a.m.

TRANSCRIPT OF IN-PERSON AND TELEPHONE STATUS CONFERENCE
BEFORE THE HONORABLE LAWRENCE F. STENGEL
UNITED STATES DISTRICT JUDGE

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I N D E X

	PAGE
COLLOQUY	4
ARGUMENT:	
By Mr. Cohen	12, 96
By Mr. Tisi	52, 99

E X H I B I T S

NUMBER	DESCRIPTION	MARKED	ADMITTED

(None marked.)

- - -

THE COURT: And we have a rather limited but packed agenda. I think the main event here is the discussion of the supplemental reports, and so we'll get to that very shortly.

In terms of where we are in New Jersey, Mr. Berman?

MR. BERMAN: Yes, Your Honor. Laurence Berman for the plaintiffs. I'd like to address two points first, if I may.

With respect to the New Jersey report, Mr. Milling will actually give you a supplement today, as there was a conference call with Judge Johnson yesterday. I was not available to participate in that, so he will be able to give you more up-to-date information about the New Jersey on-goings.

THE COURT: Okay.

MR. BERMAN: The second point I wanted to make -- and I'm not quite sure how -- how to make it -- is that the plaintiffs were a bit surprised about the audio/visual demonstrative display that was set up for today's presentation.

THE COURT: I didn't do it.

MR. BERMAN: Well, I -- we were not

given any notice about that.

THE COURT: Right.

MR. BERMAN: And, certainly, if we had known that that was the intent of the defendants, we may have chosen to make our presentations in a different format or a different manner.

THE COURT: There's no extra credit for PowerPoint (indiscernible).

MR. BERMAN: And we actually have no idea what is going to be displayed. We --

THE COURT: Right.

MR. BERMAN: Your Honor's standing order has always been, provide courtesy copies of exhibits, which we're prepared to do, for hand-up and so that the court can follow.

We -- we don't know if this is cuts of depositions, whether there's video. It's a complete surprise, Your Honor, and we just feel that we were entitled to notice and that, you know, perhaps we can reserve an objection to the manner of presentation that the defendants choose to make.

MR. MILLING: Good morning, Your Honor.

THE COURT: Mr. Milling, good morning.

MR. MILLING: Clay Milling for the plaintiff.

As Your Honor, I think, is aware, the parties are going full bore on multiple issues right now as it relates to the Taylor (ph) case, which is set for trial in late May.

We are -- have been working with the defense on deposition designations because the Taylor (ph) case involves two claims; failure to warn is where the Jackson -- and -- and design defect, while the case last year was just one claim. We're lining up the deposition of treaters.

We are -- have jury questionnaire due on the 9th, evidence list due on the 16th. So we're going as fast as we can on that.

At the same time, the defendants' motion, as it relates to the Acute Liver Failure Group, has stretched everyone thin, with depositions all over the country last week, from the East Coast to the state of Washington.

Briefing on the Acute Liver Failure Study Group issue in New Jersey, Your Honor, is due on May 9th, with only a seven-day reply -- reply period, and the parties are to be in New Jersey beginning on May 16th for day-to-day arguments on pretrials -- issues continuing until they're completed; jury selection to begin May 23rd.

As Mr. Berman mentioned, there was a call yesterday, a conference call, with Judge -- slash hearing with Judge Johnson. He wanted an update on our ability to -- to meet the deadlines in the scheduling order.

And then we had considerable discussion about the Acute Liver Failure Study Group. He is aware that Your Honor is hearing argument today. He asked when we thought you would rule, to which we said we did not know, but that the plaintiffs had asked for expedited hearing and ruling.

And he was asked whether he would like a copy of the transcript from today, and he said he would, and he asked us if we could somehow work with the court reporter to get a thumb drive so that we can deliver a transcript of today's hearing to Judge Johnson for his read.

He is currently reading the lead deposition, the plan deposition, the (indiscernible) deposition, trying to get his hands on the issue, but he has not seen the motions and, again, would like the benefit of the oral argument today.

So we're going in a lot of different directions as fast as we can. Thank you, sir.

THE COURT: Okay. Thank you,

Mr. Milling. We should be able to accommodate the request for an expedited transcript. I'll have to look into the thumb drive request.

INDISCERNIBLE SPEAKER: (Indiscernible.)

THE COURT: Okay. All right.

MR. MILLING: And Judge Johnson's pretty technologically savvy, so I -- I think just a quick call and figure out how -- how we can get it over there, no worries.

THE COURT: All right. We can do that.

All right. From the defendants' perspective, Ms. Jones?

MS. JONES: Yes, Your Honor.

THE COURT: Good morning.

MS. JONES: Good morning. Ms. Jones.

The -- the -- I do not have anything -- additional comment. I think that Mr. Milling accurately reflected what's been going on in New Jersey.

There has been a significant amount of information or documents transferred between both courts, and so I want to -- we want to be sure that we give Your Honor what he wants as well as what we're doing in New Jersey as well.

So, for example, the -- Judge Johnson

does have copies of all of the briefing that's been made in this court in the MDL.

One of the things that Judge Johnson has been provided that the plaintiffs have actually been providing to him in realtime are transcripts of all the depositions as they've been taken.

So we -- we have copies of those, to the extent that Your Honor would want those or want to be furnished those. And so I just want to make sure that all of the information is being shared to the extent the court wants it.

THE COURT: Okay.

MR. MILLING: Lastly, just in terms of coordination, Judge Johnson was -- has also been provided Your Honor's rulings on motions in limine. (Indiscernible) were helpful.

And so we -- as Alyson mentioned, we are trying to keep both Your Honor and Judge Johnson in the loop, given where everything seems to be with the litigation generally.

THE COURT: All right.

MR. BERMAN: I just want to add, Your Honor, you were previously provided with Judge Johnson's scheduling order. I think it was the order that was dated January 29th. And that's the order

that provided that the Kemp motions, which is similar to Daubert, would not be filed until the depositions were completed. So what he has been provided with has been the courtesy copies of the filings in this court.

THE COURT: Okay. Thank you.

MR. BERMAN: Thank you.

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(Pause)

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THE COURT: Okay. Why don't we talk about the supplemental reports. Who's going to argue that for the defendant?

MS. JONES: Yes, Your Honor. David Cohen from our office is going to argue on behalf of the defendants.

THE COURT: And are you responsible for all this equipment, Mr. Cohen?

MR. COHEN: I am the guilty party, Your Honor.

THE COURT: Okay.

MR. COHEN: Guilty -- we -- we had presented an argument to Judge Johnson in September on the Kemp motion, and we used audio/visual, and there was no objection at that time.

THE COURT: Okay.

MR. COHEN: We did not, for this purpose, Your Honor, use any video because of the time frame involved from the depositions. So the purpose of the -- of the visual -- we haven't used -- we're not using videotapes. The purpose of the presentation of the visual was to, essentially, be more efficient since there has been such a mountain of evidence that has been produced in such a short period of time and we have a short period of time today to argue. So if I may?

THE COURT: Thank you. Now, in terms of our schedule, I have a sentencing that was scheduled at 2:00. I have a -- a commitment at 12:30. So we'll -- we'll take about an hour on each side to -- to get this done.

Mr. Tisi?

MR. TISI: Judge, may I approach the bench with -- with -- with Ms. -- with Ms. Jones for a moment?

THE COURT: Sure.

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(Whereupon, a sidebar conference was had between 10:19 a.m. and 10:21 a.m.)

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THE COURT: All right. Mr. Cohen.

MR. COHEN: Thank you, Your Honor.

The 19 so-called low-dose cases published by the Acute Liver Failure Study Group in the Larson 2005 paper, in our view, cannot reliably support an opinion -- an expert opinion that 4 grams or less of acetaminophen per day causes acute liver failure.

I'd first like to start by posing a few questions and trying then to answer them with reference to actual documents in evidence, which I hope will assist this court in making an assessment of the underlying reliability of this evidence as part of its gatekeeping role under Federal Rule of Evidence 702 and Daubert.

The questions I would like to pose are as follows:

First, what is the design of the ALFSG Larson 2005 paper, and can it be used to establish causation?

Second, what is the methodology that was used to identify the low-dose cases in Larson 2005?

And, third, are there flaws in the methodology that make the low-dose data unreliable evidence of causation?

The plaintiffs' reliance, as the court is aware, of this evidence is part and parcel of their core medical causation theory in this MDL; namely, that recommended doses of acetaminophen caused plaintiffs' liver injury or liver failure.

And to prove this theory, the plaintiffs and their experts rely upon a single paragraph in the Larson paper, which is here. This is the abstract, which is that. And this single paragraph is the quote, unquote, low dose.

And when we refer to "low dose" today, Your Honor, I'm referring to the way in which the ALFSG in the paper defined "low dose," which is at or under 4 grams of acetaminophen per day.

At the Jackson trial that we had in New Jersey in September and October of this past year, the plaintiffs' principal hepatologist, Dr. Kaplowitz, testified to this data, and virtually all of the plaintiff experts cite the Larson 2005 paper and the low-dose cases in their reports.

Dr. Davern, one of their experts, is a coauthor of the paper, and he testified at his MDL deposition that these 19 cases establish causation.

And, finally, as Your Honor may recall, there has been much reference made by plaintiffs to

the FDA Working Group report on acetaminophen, and that report also references the Larson 2005 paper and the 19 low-dose cases.

This litigation sinks or swims on the claim that 4 grams or less of acetaminophen causes acute liver failure. That, in turn, relies on the plaintiff expert opinion testimony on causation, which, in turn, relies on the evidence in these 19 cases.

Plaintiffs' experts cite this article because it is the only study of acute liver failure that reports low doses of acetaminophen ingestion and ALF. They cite to it because it was published by the ALFSG, which they describe as, and their experts testify as, the most important study of acute liver failure in the United States.

I'd like to make some preliminary observations, if I can get this right, before we talk about the study --

Excuse me.

Thank you.

-- about the context.

In 2005, when the study was published, there were 28 billion doses of acetaminophen purchased by U.S. consumers. 28 billion with a B.

8 billion of those were single ingredient over-the-counter acetaminophen products. And that's from the FDA advisory committee.

Second, Larson 2005 low-dose cases essentially stand alone. No other group of researchers anywhere in the world have claimed to have discovered this many cases of ALF attributed to this dose of acetaminophen ingestion.

And, third, since 2005, since that one paragraph was published in Larson, the ALFSG has not published any follow-up studies on these cases. It bears reminder that the study itself, the paragraph, does not discuss specific cases. It does not discuss how the ALFSG identified and evaluated those cases, and since 2005, there has been no information forthcoming from the ALFSG on these 19 cases. McNeil asked for information but was rebuffed.

Now, the first question I'd like to address is, what is the ALFSG, and is it capable of establishing that low-dose acetaminophen ingestion causes ALF?

The ALFSG is comprised of a collection of cases that were collected on case report forms. We're going to talk a lot today about case report forms or CRFs.

Here is how Dr. Larson, the lead author of the paper, when asked by plaintiffs' counsel how she got the data, responded: The data was collected on paper case report forms that we had identified specific things we wanted to track.

So yes, the ALFSG is a series of case reports, and they are reported -- and they are described in the ALFSG protocol, known as the Manual of Operations, as case report forms.

We will actually look at one of those forms in a little bit, but the point I want to make here preliminarily is that the -- is that the ALFSG uses the term "case report" to describe its own data.

Now, Dr. Larson confirmed this, to confirm the design of the ALFSG, at her deposition, and -- where she said -- and then there are things called case series, which are, say, a collection of case reports? And she said, yes, correct. And the ALFSG, as a registry, is, essentially, a series of cases? Correct.

Dr. Larson then confirmed that the ALFSG does not have a control group. Correct. She said, it's not designed as a controlled study. And then she was asked whether it's ever published risk ratios. Those would be such as odds ratios or

relative risks. And she agreed. That's correct; we are not designed to do that, was her testimony.

The ALFSG, therefore, as Dr. Larson testified at her deposition, was not designed to answer the question of whether acetaminophen ingestion of 4 grams per day in divided doses causes ALF.

So the ALFSG, therefore, is not a clinical trial. It is not an analytical epidemiological study with a control group. It is simply a collection of case reports, known as a case series.

So let's turn to the -- specifically to the Larson 2005 paper. This paper was not designed specifically by the ALFSG also to answer the question of whether low doses causes ALF. Dr. Lee conceded that.

Question: And can we agree that Dr. Larson -- that Larson 2005 was not designed to answer the question of whether acetaminophen ingestion of 4 grams per day in divided doses causes ALF? Dr. Lee responded, that's correct.

Dr. Larson said exactly the same thing, a little bit differently, but let's go through it.

And in that protocol, you have in it, in

front of you -- there is not a single reference to low-dose acetaminophen ingestion, is there?

And that's the Manual of Operations.

Over objection, she answered, that was not the design of the study.

Dr. Lee acknowledges that the paper does not report a statistically significant association between acute liver failure and acetaminophen ingestion of 4 grams or less.

He was asked this specific question, whether there were any risk ratios reporting statistically significant association between ALF and low dose ingestion, and he said, it's -- there is none.

Before moving to the low-dose cases themselves, I'd like to offer two observations about why the design of the ALFSG is so important to the question of causality presently before the court.

First, case reports and case series cannot establish causal associations. That's a well-accepted principle in science and medicine.

Second, if Drs. Lee and Larson themselves believed that the case report data in the ALFSG and, specifically, in Larson 2005 established a causal relationship between low-dose ingestion of

acetaminophen and ALF, they would have said that.

Instead, let's look briefly at what they published and have told the scientific community that acetaminophen -- about acetaminophen ingestion up to 4 grams a day.

And I want to just preface this by pointing out that the Larson paper, which was published in 2005, is based upon data collected by the ALFSG between 1998 and 2003. The article took two years to write and to publish. So the period of which they -- when they collected data is 1998 to 2003.

In 2003, Dr. Lee published this with one of his colleagues, Dr. Schiodt, S-c-h-i-o-d-t. And in this paper, he -- they -- these two authors wrote, taken within recommended doses, maximum 4 grams per day, acetaminophen is a safe drug.

We asked Dr. Lee about that statement at his deposition, and we asked, does it say that? It does. Is that what you wrote 13 years ago? Yes. You stand by that in general? Yes, we all know that it's a safe drug in general.

We asked him again, do you stand by the article? I would think it represents our thinking in 2003, yes. And you haven't withdrawn it? No, it's a

book chapter.

Actually, it's a series that comes out either on a monthly or quarterly basis, and so it can be, of course, annotated and updated.

Dr. Larson also wrote in 2007 an article on acetaminophen hepatotoxicity. Now, this is, of course, two years after Larson was published -- Larson 2005 was published.

And in that article, she wrote, acetaminophen is effective and safe when consumed as recommended, 1 to 4 grams per day.

We asked Dr. Larson about that. Did you write that? I did. Do you stand by that? I do, with some caveats -- which we're going to come back to. And since this article has been published, Dr. Larson, have you withdrawn that statement in any articles you've published since then? No. And is this article written two years after you -- you published your 2005 paper? Yes. So at the time, you knew about the 19 cases of low-dose ingestion? And she said, yes.

Now, Your Honor, in 2009, Dr. Lee was invited to the FDA to testify before the advisory committee on acetaminophen. He was asked many questions about that during his deposition by

plaintiffs' counsel.

But he was also asked at that testimony at the FDA the following question: Is there a point -- this is a question to Dr. Lee at the FDA advisory committee. Is there a point where you would opine that acetaminophen is a safe drug or that you think would be a reasonable, safe dose for people to take? And Dr. Lee responded, I guess I'd rather not be pinned down; that's a tough one.

Now, we asked Dr. Lee about that. Is that what you told the FDA? He said, it looks like it.

Now, in 2013, Dr. Lee made a presentation at the American Association for the Study of Liver Disease, known as the AASLD. We've heard a lot about it. They had an annual meeting, as they always do. He was invited, and he even was invited to give a presentation in honor of Hy Zimmerman, known as the Zimmerman presentation.

And during his presentation, he -- he elected -- I should preface this. He elected to focus his presentation on acetaminophen. And he showed a slide, number 21, and at the end of his presentation -- and his presentation was virtually all on overdose and the problem of overdose and how

to stop overdoses of acetaminophen causing liver injury, which everybody acknowledges happens.

But he said at the end in his slide on controversies remaining, low-dose ingestions, question mark, as a controversy remaining.

So we asked him about this at his deposition. And so you see there, so you wrote in the second bullet point, low-dose ingestions, question mark? Right, right. Why did you write it as a controversy? And this is what he said, because it's still uncertain; as you -- we just discussed a moment ago, that these -- that we -- we haven't been able to prove these completely, but there's certainly evidence in favor of them existing.

And he went on -- I'm not Mr. Finlay (ph). Well, what is a controversy in medicine, we asked him. It means that people disagree; they have friendly disagreements. And there's nothing wrong with that, right? That's right. For physicians and scientists to disagree about science? And his answer was, there's uncertainty.

Since collecting the 19 low-dose cases between 1998 and 2003, this is what Drs. Lee and Larson have said and published to the medical

community.

And I submit that if the methodology used by the ALFSG to identify these 19 cases in a paragraph in Larson 2005 were reliable and convincing, I don't know how Dr. Lee could have published in 2003 an article stating that 4 grams are safe.

I don't know how Dr. Larson could have published two years later, in -- after the article was published, in 2007, that 4 grams are safe.

I don't know how Dr. Lee would have been able to tell the advisory committee in 2009, when asked about a safe dose, that he'd rather not be pinned down.

And I don't know how Dr. Lee would have told the annual meeting of the AASLD in 2013 that this is still a controversy, a remaining controversy.

Dr. Lee certainly would not have explained his prior writings and statements in this proceeding as he did, using the words that -- we haven't been able to prove these, and there is uncertainty.

Where there is a lack of proof and a lack of certainty, I submit that there cannot be scientific reliability about causation.

I'd now like to turn to the second question of the methodology of the ALFSG and, specifically, Larson 2005. And so, as I mentioned a moment ago, we're going to look at a case report form to understand what went wrong.

These are the case report forms. This is page 1. They're used -- they were designed by the ALFSG. They're designed to enroll patients by the different study sites into the registry. And there's -- reminder, that these do not become part of the patient chart.

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(Phone ringing.)

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INDISCERNIBLE SPEAKER: I'm sorry. I thought it was off.

MR. COHEN: After the CRFs are filled out by the study coordinators or the study investigators at the different sites, they were then -- at the time the Larson paper was written, they were faxed to UTSW in Dallas.

A physician reviewed the forms at UTSW. The physician may have queried the sites for additional or missing data or resolution of ambiguities. That's what Dr. Lee said they did in

his declaration.

Once the query responses were returned, if there were any, the data in the CRFs that are filled out in these forms was then entered into a computer database.

And it's important to recall what they said about this. It was entered in a head-down data entry, which I just now have learned means that somebody types the data into the database, no questions asked. It's -- as it comes in, it gets just put into the database without any questions.

Now, the Manual of Operations that the ALFSG and Dr. Lee created for the ALFSG emphasized getting good data and being careful. Here's what he wrote, as the saying goes, garbage in, garbage out; the data is only as good in the way in which it is collected. And at the end of this quote here, he says, this is vital; nothing will sink this project like poor data collection.

THE COURT: And who said this?

MR. COHEN: Dr. Lee in the -- in -- in the Manual of Operations -- I can't say it was Dr. Lee. The ALFSG Manual of Operations. And the specific cite for that, Your Honor, is the First Edition, 1997, page 12.

We can -- we have copies of everything we can give you, by the way. At any moment you need a hard copy, we have everything.

There are several key sections for the court, I think, to understand that are relevant to the question of the reliability of the acetaminophen dosing histories in these 19 cases, so let me just walk you through them very quickly.

Section 13 is the date of onset of hepatic encephalopathy or coma. This is the -- this is the -- they have four grades, one through four. In order to be enrolled in the ALFSG, you had to have hepatic encephalopathy, which means altered mental status.

They also tracked risk factors, and one that they tracked was ETOH, which is alcohol. Also important.

Another thing in the case -- case report form is a section called Medications. And here you can see -- and I meant to highlight it, but I -- I failed to do it -- that it's -- it's medications last six months, including toxins, herbs, mushrooms, and OTC meds. That's anything over the counter, even vitamins.

And then, finally, in section 18,

relating to acetaminophen specifically, they called this section Acetaminophen Overdose. It bears worth noting that in the case report form, they never -- they never had a section about low dose. They assumed it was going to be all overdose. And so they called this section Acetaminophen Overdose and called for additional information on that.

And then, finally, they had a section called Tox Screens, which we'll talk about, and the acetaminophen level. And that's the blood level of acetaminophen in patients when they get to the hospital.

And then the last thing here, which are blank, of course, since this is a blank form, are -- they provided two comment sections on the two different parts of the form.

Now, the focus of Larson 2005, as I mentioned a moment ago, was on acetaminophen overdose. Of the 275 patients in the paper, 256 were overdoses. There's only that one paragraph that I described and showed earlier on page 1368 that describes these 19 cases.

Dr. Larson was the primary author, and Dr. Lee verified that the paper was written from a spreadsheet.

Dr. Larson confirmed that the paper was -- was written from a spreadsheet and, specifically, the 19 cases.

So -- and tell us, Dr. Larson, how did it come about that these 19 cases were identified? Answer: When we looked at this data, we noted that there were several cases, 19 -- I think there were actually a couple more -- that had reported taking less than 4 grams --

And I've highlighted "reported" because these were reported --

-- which was at the time considered the therapeutic limit, and we just wanted to look at them and see if they differed from the patients who had taken more.

And then Dr. Larson said -- we -- we followed up and said, well, you said, when we looked at this data. And she responded, and looked at all the doses that we had available; that's when we saw that there was some cases that fell outside of over the 4 grams.

In other words, she was looking at a spreadsheet, and here, she -- she confirms that, which was marked as Exhibit -- as an exhibit to the deposition. And, in fact, that's what Dr. Lee

verified in his declaration of January 30, 2016.

So it's important to keep that in mind because what happened was, she never looked at the case report forms when she wrote the paper. They were never even sent to her. And that she confirmed at her deposition.

And as you said earlier today, you didn't write the paper from the case report forms? No, they were at the main site --

That was in Dallas. She was in Washington, the state of Washington.

-- and questions went to Dr. Lee and other authors at the site if I had questions in the database.

And she also didn't have a protocol that was designed to help her confirm the low doses in these 19 cases. Quote, there was no protocol specifically for those 19 cases, other than the -- the main protocol, which is the Manual of Operations, which has nothing about low-dose cases.

And, in fact, she confirmed, in the Manual of Operations, there is nothing about low-dose acetaminophen ingestion. No protocol, no mention, nothing. That's their protocol.

Dr. -- excuse me. Dr. Davern, who is a

plaintiffs' expert in this case, Your Honor, in the MDL, is a coauthor on this paper. I'm going to mention him very briefly.

He testified at his deposition that he never saw the low-dose CRFs, never evaluated them, did nothing to verify the doses, and did not discuss the low-dose cases with any of the site investigators, with Dr. Lee, or with Dr. Larson -- that's at his deposition, page 41, line 10 to 42, line 2 -- that he did not see any written analyses of these cases, these 19 cases, before they were published. And he -- and that's at page 42, lines 3 to 21. And he was a coauthor, and he reviewed drafts, as he testified, of the manuscript.

Now, the part of the CRFs that's most relevant to whether a -- low-dose case information relating to acetaminophen is, of course, the acetaminophen information in the form.

And Dr. Lee testified that the credibility of these 19 cases rises and falls on these low -- on the dosing histories. Well, the basis for the classification is the credibility of the dosing history that's in the CRF, correct? Answer, the question is correct as you phrased it.

Now, I'd like to turn to the third and

final question, which is, are these cases flawed as a result of the methodology that was used to write this paragraph in this paper?

And as a just quick background, in this proceeding, Your Honor, over very strenuous objections made by the plaintiffs and after almost two years of litigation in Texas, we have discovered evidence about cases that has never been disclosed before, not to the FDA, not to the NIH, not to the editors or peer reviewers of the Journal of Hepatology, which published the article.

We have also now received testimony that has never been heard by anyone in the scientific community. Dr. Lee admits publically for the first time that three of the 19 cases should be withdrawn as low-dose cases.

Here is the first one. And what we've done here is just X'd out the first two digits of the CRF number so that we don't have to have anything sealed, because UTSW requires that that information not be disclosed without confidentiality -- due to confidentiality.

So this is -- we're going to refer to them as the last three numbers of the CRF number. So this is 026. And I have a binder, which plaintiffs'

counsel actually prepared. If they don't mind, I'll just hand it to the court. CRF 026 is at tab 19. May I approach?

THE COURT: Sure.

MR. COHEN: Thank you.

THE COURT: Thank you.

MR. COHEN: And everything I'm going to show you is on the screen, but I just wanted you to have it.

And you can see here, in the Medications and in the Acetaminophen Overdose section, what was written in was, a handful, by the study investigators, handful of Tylenol. Not, obviously, a precise dose. Dr. Lee withdrew that case as a low-dose case.

THE COURT: Well, 6 is still a pretty low dose, isn't it?

MR. COHEN: It's 50 percent more than the maximum therapeutic dose. Sure, it's not 10 grams, but it's not 4 grams, and the criteria for that paragraph was 4 grams or less.

And I will also submit to Your Honor, we can present evidence, not today, about that case, which puts that 6-gram dose into substantial question. But I did not prepare to do that today.

And the reason I didn't prepare to go into that case in very great detail with Your -- with Your Honor is because Dr. Lee has withdrawn that case from the publication as a low-dose case.

Now, the second case he withdrew is 035, and here are some of the relevant portions of it. And that's because the study site investigators on the CRF had written Macrobid in three different places -- actually, four. There's a reference to nitrofurantoin in the Medication section. That's the same as Macrobid, so in four places.

And that is an antibacterial agent known to cause liver injury and acute liver failure, but it got in and was published as one of the 19. And Dr. Lee has concluded that that case should be withdrawn.

THE COURT: And he did that, really, on the basis of that adduct test, right, that was conducted after the Larson paper?

MR. COHEN: He says that the adduct test may have helped him understand more about these cases.

THE COURT: All right.

MR. COHEN: But what he also testified was that this had an alternative cause, which was in the CRF, but was not used in 2005 as a basis to

exclude it.

THE COURT: All right.

MR. COHEN: It was ignored. And, of course, as you know, they didn't have adducts in 2005.

THE COURT: All right.

MR. COHEN: And we'll talk about adducts later.

So we're going to look at one more case. I'm not going to go through the details yet of this case. I will in a few minutes. But this case involves a very unfortunate, tragic situation of a 35-year-old female, who was drinking substantial quantities of alcohol, took a Tylenol overdose, as written in the record, then took d-CON -- now, d-CON is rat poison -- in a suicide attempt noted in the CRF and died very tragically.

And she was -- a death note was sent to the L.A. coroner's office by the medical institution, signed by a doctor and a second person, indicating she died of acetaminophen overdose.

And so when we presented all that to Dr. Lee, when asked, well, given all that data, classifying this case as somebody who simply took acetaminophen as directed, he said, I would have to

say no.

And so we got -- after these three cases with Dr. Lee in his deposition, we asked this question. This comes right after this d-CON case. We call it the d-CON case, just to remind ourselves. So you withdrew this from that classification, correct? Question: So we've withdrawn three cases, right? And his answer was, yes.

Now, Dr. Larson, the first author on the paper and who wrote the paper, withdrew two cases immediately. Dr. Larson attempted to defend the d-CON case, case 042, which Dr. Lee had agreed to withdraw. I will show you this testimony, because it's an outstanding example of why this paper and this discussion of 19 cases is methodologically flawed.

Let's look at the case report form 042, which is at tab 14 of your binder, but you can look at it on the screen.

And here, you can see, in section 13, that this patient came in with hepatitic coma -- so she had altered mental status -- and proceeded very quickly to a very serious state of -- where she became comatose very quickly.

She was drinking 80 grams of alcohol a

day for an unknown period of years. 80 grams.

The medication list in this CRF for this patient, Your Honor, is completely blank. There's not a single acetaminophen product listed, not Tylenol, not Lortab, not Vicodin, not generic acetaminophen. We don't know the date last taken. We don't know the total dose. We don't know duration. Everything is completely blank in the CRF.

The only reference to her dose is in the Overdose section, where somebody wrote in 1,200 -- 1,200 milligrams. That's 1.2 grams. I'll get back to that.

And the acetaminophen level, she had a level of 120, and -- and -- and that number may not have relevance in the abstract, but the typical level -- depends on the -- on the institution -- is anywhere -- for recommended dosing of acetaminophen, the maximum level ranges from about 20 to 30. She was at 120.

Her history was given by the father and the investigator. The treating doctors, the study -- the study investigator for this site who enrolled this patient, here's what they wrote: 35-year-old female, Tylenol overdose and d-CON ingestion along with heavy alcohol use several days prior to a

suicide attempt.

Dr. Larson --

Oh, last part. This is the coroner's office record -- or the -- the note to the coroner's office on a coroner's form from the county of Los Angeles, where you can see acetaminophen overdose written four times by the doctor and whoever else submitted that form. Two people signed it.

So we asked Dr. Larson. First of all, she said, well, I wasn't reviewing the CR -- the CRF. She didn't review all that information we just saw.

So we asked her, okay, well, how do you -- even though you aren't reviewing the information -- she knew it was 1,200 milligrams because she had a spreadsheet -- well, how do you take 1,200 milligrams?

And -- and let me just explain that. Tylenol or acetaminophen comes in 325- and 500-milligram doses. You can't multiply those in whole tablets in any combination to get to 1,200. We -- we tried. We did some simple math. It doesn't work. You have to cut up pills to get to 1,200.

Somebody making a suicide attempt, where the history is being recorded by the father, is unlikely cutting up pills to commit suicide and get

to 1,200 milligrams of acetaminophen.

So she -- she admits it's an incorrect dose.

And then, why -- I asked her, why would the Tylenol overdose referenced in section -- why was that specific reference, the reference we saw by the treating doctor, never queried, the reference to Tylenol overdose? I don't know, because the main site was the location where all -- where -- where these were all initially vetted. So you don't know why this was not queried in 2002? No, I do not know. Or in 2005 when you wrote the paper? No, I did not have the case report forms.

And then, of course, she knew about the fact that it says acetaminophen overdose in four places in the -- in the report of the death to the L.A. coroner's office. We asked her, do you have any basis to dispute that? No.

And, finally, she said -- we asked her, you would not present this case today based on the CRF and the death? She said, it would have been more carefully queried today than it was 14 years ago. You're on the causality committee now, right? Yes. And as a member of that causality committee -- answer, we would have queried it. And you would not

today categorize this case of a low-dose case of acetaminophen causing ALF, correct? Answer: We would have potentially have called it an unknown dose.

Your Honor, this testimony from Dr. Larson, I think, highlights and shows the flaws in the methodology that was used to evaluate and query or not query the acetaminophen dose information in the CRFs.

Like Dr. Lee, Dr. Larson now believes that at least three out of these 19 cannot be classified as ALF from low-dose ingestion of acetaminophen. That's almost 16 percent error rate. That's an error rate unacceptable in any field of science and, specifically, in medicine.

Let's look at one more CRF. Let me see. Hang on, please.

- - -

(Pause)

- - -

MR. COHEN: And it's case 008, and it's at tab 9. Now, Dr. Lee testified that the data in the CRF for this case do not fulfill criteria for assigning acetaminophen as the cause of the patient's ALF.

"Criteria" means -- in the study, to be assigned acetaminophen, you had to take either more than 4 grams, you had to have an ALT over a thousand, or you had to have some level of acetaminophen in your blood when you came into the hospital. Those were the attribution criteria for acetaminophen.

Matt, could you show us Lee 299? Do you have that handy?

Dr. Lee explained that the study's prespecified criteria for attributing acetaminophen to that case were waived. Let's see if we can find it.

And I'm sorry. It may not be here, so I'm going to read it into the record. That's the problem with technology.

Ah, here it is. Found it.

Dr. Lee testified --

INDISCERNIBLE SPEAKER: I think I (indiscernible).

MR. COHEN: Oh, you're right.

THE COURT: Go back one.

MR. COHEN: Yeah, it keeps jumping on me.

INDISCERNIBLE SPEAKER: Forward. Forward. Forward.

MR. COHEN: Yeah, that's it.

So he said he waived it, he said. He waived the criteria. So we said, who waived it? That would have been me. Where is the waiver discussed in the CRF? Oh, this was usually a telephone call from the site. To who? To me, from the site investigator to me. Is that telephone call documented in any part of the CRF or any other documentation you can provide to us today? This was the first six months of the study being started in 1998. Well, how do you recall this was waived, given the age of the case? Answer: Because that was a common practice, I would say, in the beginning; if they were -- if somebody had the data from the previous hospitalization and it looked like a good case, we were eager to get cases in those early days, and we -- I might have accepted it even though the labs didn't quite compute.

Frankly, Your Honor, I found this testimony to be astonishing. It clearly shows bias in methodology. A single person had a -- in an unblinded fashion simply waived criteria for assigning acetaminophen, didn't document his waiver, and never informed the peer reviewers and the readers of the Journal that this was, quote, a common

practice in the early days.

When a researcher admits that he's collected data in violation of his own predetermined criteria because he's eager to get cases and then doesn't disclose it, I submit, Your Honor, that is bias in research and bias in reporting.

But don't believe me on that. Here's Patricia Robuck, who the plaintiffs also have sponsored as a non-party witness. She was the program officer at the NIH for the ALFSG, and she testified about this very issue.

Are you aware, in the ALFSG study, if scientists could unilaterally waive -- decide to waive qualification requirements and admit a subject or enrollee? Answer: No one is allowed to do that, but no, they are not allowed themselves, individually; that's what being part of a protocol is all about; you must follow the protocol.

Now, Dr. Robuck told us that even if the waiver in a study was performed, it must be documented. Let's go back to the question of waiver. If an individual scientist decided to waive some of the qualifying criteria, any or all of the qualifying criteria, you would expect that waiver to be documented in the record, wouldn't you? Answer:

Yes. Question: And it's important that it be documented, correct? Answer: Yes.

Dr. Robuck even said the NIH expects a lack of bias in research and reporting and the NIH also expects from its grant recipients, of which the ALFSG is one -- it is true, a lack of bias in the reporting? Answer: Yes. A lack of bias in the researching? Yes.

Dr. Lee's waivers, which he testified he never documented, which he did so commonly in the early days to get cases, clearly do not conform to Dr. Robuck's testimony on what the NIH expects from its researchers.

Now, Dr. Larson was asked about this same CRF, the one in which Dr. Lee unilaterally waived criteria and didn't document. Now, because he didn't document it, Dr. Larson didn't know about the waiver. She didn't know. Therefore, unlike Dr. Lee, Dr. Larson testified that although this patient was properly in the ALFSG, because the patient had ALF, the patient would not properly be included in the paper.

And here's what she said. You have study criteria for a reason? Yes. And if patients don't meet those criteria, they should not be in the

study? As I said, this would be queried more carefully -- today more carefully. Question: This patient should not be in the study? Answer: This patient is appropriate for the study; this patient would not be included in the paper. In the paper? Yes.

So -- so Dr. Larson has now conceded that there are four cases where the -- of the low-dose cases where the methodology was so flawed that today she would say they don't belong in the paper.

That is an error rate of over 21 percent. That's not acceptable in medicine or science. No one -- no one wants his or her doctor to practice medicine with a 21 percent error rate.

I have now shown you four cases that are so obviously flawed that Dr. Lee, for three of them, and Dr. Larson, for four of -- four of them, would not today characterize them as low-dose cases.

And plaintiffs have made a lot about the fact that the FDA and the NIH have reviewed and approved the methodology of the ALFSG. It's all over their papers and all over the declarations that were written for these experts. Yet Dr. Lee tells us that these CRFs were never provided to the FDA or to the

NIH, so these agencies had no reason to know about this.

Okay. You never sent -- this is to Dr. Lee. You never sent the CRFs for the 19 cases to the FDA? Answer: Not that I'm aware, no. Question: And you never sent them to the NIH? No.

Your Honor, there's a more grotesque aberration of science we still need to discuss with respect --

THE COURT: You're going to have to wrap it up shortly.

MR. COHEN: -- to these cases.

I will.

In June 2009, Dr. Lee told the FDA advisory committee that the ALFSG was going to publish Larson 2. All right? And he said that. Here's the statement from his testimony to the FDA. You can see Larson 2. That's in June 2009, and here's the slide that he showed; we plan a Larson 2 paper. Okay?

And, in fact, what we found was that they actually started looking back at the Larson 2005 data in 2009 as part of something they called the Data Clean Project. And that's an email that describes -- or that conveys some spreadsheets to

Dr. Lee about Project Data Clean.

And it takes a little bit of me to explain this to you, so bear with me, if you will, and I'll do it as quickly as I can.

But Dr. Larson testified that the -- they wanted to make the data as clean as it could be, presumably for Larson 2.

And here is the spreadsheet, 3 -- UTSMC30059. And it has colors, and one of the colors is gray, and gray means excluded from the study for some reason.

This is a medical student who's going through the data at Dr. Lee's request and looking and seeing, how is the data from Larson 2005?

And so what he concluded was that case 042, the d-CON case, should be excluded. It was in gray. And he concluded that another case, 051, should be excluded. It was in gray.

And he concluded in the green, a case, 116, should be re-categorized not as -- not excluded from the ALFSG or the registry but re-categorized as an overdose case because of a dosing -- a problem in the dose -- the day -- the day of the -- the days of dosing.

And then they put together this

spreadsheet, which is -- which has a column called Delete on it. And here, you can see case 042, (indiscernible) d-CON poisoning, in the Delete column.

And we asked Dr. Larson, what does the graying indicate in the spreadsheet, and that spreadsheet has suggested this was excluded. And we asked Dr. Larson, so according to the spreadsheet, this was excluded?

And this is one of the other cases I just talked about. I'm going to try to hurry this along.

And she said, yes, it was excluded in 2009. And -- and -- and then we asked Dr. Larson again what this all meant, and if you go back to this spreadsheet, does it indicate that this was reclassified from a low dose to an overdose? That's the green case that I showed you, 116.

And she eventually said -- do you remember this? I mean, I remember they were doing it, yes, that they had re- -- reclassified that case as an overdose.

And so we asked her, you were reevaluating -- the ALFSG was reevaluating the Larson 2005 cases as part of the total second group? Yes, I

believe that's true. This is in 2009.

And then she said, so let's -- we then go back to the 042 case, and she says, I'm asking you -- or I asked you, I'm asking you, in 2009, you and Dr. Lee and the ALFSG decided that it should be deleted for Larson 2? And that she -- and she answers, that would appear what this says.

And so, therefore, in 2009 -- this is case 116. It falls out. That's the 116 case. I'm just going to hurry this along.

So I asked her, don't you think it's important information to the question of whether or not these are reliable cases of low-dose ingestion at 4 grams per day or less, this Data Clean, this -- all these spreadsheets showing this reevaluation? And she admitted, yes, it's important.

But here's the point, Your Honor. Dr. Larson doesn't mention Project Data Clean in her declaration. Dr. Lee doesn't mention it in his declaration. They don't mention that in 2009, they went through this evaluation process and excluded cases.

And here's how Dr. Larson described it. So nobody ever learned that these low-dose cases had been excluded by the ALFSG other than the ALFSG?

Answer: This just hasn't been done yet. Question: In 2009, when the ALFSG decided to delete these two cases, did you have any conversation with anybody at the ALFSG about correcting Larson 2005? No. Did you think about sending an errata or an explanation; hey, the data has been reanalyzed, and we've excluded five cases, and two of them were low-dose cases -- because we went through three others that were not low dose. No. And that's never been made public until today? Answer: Well, yes, that's probably true. Never told the FDA? No. Never told the NIH? No.

We didn't examine today every single CRF with Dr. -- we didn't examine at their depositions every single CRF with Dr. Lee and Dr. Larson. That would have taken a couple of days. We didn't have a couple of days. They're non-party witnesses. There was a lot of resistance to us having time to depose them, but we deposed them as best we could.

And what we now have learned is that we already have, at a minimum, either 16, up to 21 percent of the -- of the cases being excluded based upon the methods -- based upon the methods used to publish these data.

And what is important about these flawed data is exactly what Dr. Robuck has said. Can you

point to me any NIH document where NIH says, there's certain amounts of data that we can accept as flawed? No. Can you point me to any NIH protocol where they say, eh, a little bit of data -- bad data is okay? No. Can you point me to any -- any NIH protocol, any NIH regulation, any federal regulation which supports your statement and your testimony earlier that you said a certain amount of data problems are okay; can you point me to that? No.

And, finally, Dr. Lee wrote to a U.S. senator in 2006 in connection with a clinical research study involving a different drug, not acetaminophen, which was believed to cause liver injury. Dr. Lee wrote to the U.S. senator about the company's sponsorship of that study.

The company is certainly to blame for a faulty study, and no one should consider that any flawed data in a study -- and one should consider that any flawed data in a study throws out all that data.

In conclusion, Your Honor, science requires setting up a hypothesis, designing a study to test it, and testing it. Acetaminophen causing ALF at low doses was not the design of the ALFSG, and it was not the design of Larson 2005, as both Dr. Lee

and Larson testified.

Where a study is not designed to answer a question of causation, data pulled from that study cannot be later used to answer that question. This is not an analytical epidemiological study. That is not what the ALFSG is all about.

But even if we accept that this is the only valid way of examining acute liver failure and low-dose acetaminophen, which we dispute, the methods used here to collect and analyze the data with respect to the dosing of acetaminophen in these 19 cases was obviously highly flawed.

We have seen now several examples that even the lead principal investigator and the lead author of the paper have testified that they would not stand by those cases today as low-dose cases.

Dr. Lee's testimony in a short deposition produced the astonishing admission of a 16 percent error rate, and Dr. Larson admitted to a 21 percent error rate.

The FDA didn't know about these cases. The NIH didn't know. The readers of Hepatology didn't know. The only people who know are us, and sometimes flawed studies get past peer review, and this is one example.

When Dr. Larson wrote in 2006, one should consider that any flawed data in a study throws out that data, he was right. That principle applies here.

Your Honor, there are some additional issues that I would like to reserve a few minutes of time to discuss, if I may be permitted, after counsel for plaintiffs presents.

THE COURT: Let's see how we are with time.

MR. COHEN: Thank you.

THE COURT: Thank you.

Mr. Tisi.

MR. TISI: Judge, I'd like to, first off, thank the court for agreeing to hear this on an expedited basis. It's, obviously, important to the parties as a practical matter for not only this trial and the evidence that will come, that we have to amass for a September trial, but it's also important, as Mr. Milling pointed out, I think Judge Johnson is looking, if I can be so bold, to some of the things that we're doing here.

As I also indicated, we were taken off -- a little bit off with the PowerPoint presentation, but I'm going to do the best I can to

jump around.

I did prepare for Your Honor a binder, as we -- as has been typically done in the past for exhibits that we might refer you during the course of -- of this argument. And with your permission, I would --

THE COURT: Sure.

MR. TISI: -- like to hand it to you.

THE COURT: Alyssa (ph), you can take it.

Thanks.

MR. TISI: The question that we have before the court is -- is pretty straightforward; does Daubert require the court to relitigate -- or allow the court to relitigate, as defendants have suggested the court do, the validity of a study like this that has passeded -- passed not only peer review by the -- by the Journal of Hepatology but, as you will hear, the National Institute of Health? And this data has been presented to the -- to the FDA.

Specifically, you're going to be asked whether or not we should wrap 11 cases or 17 cases into the trial of this single case and whether or not this is a -- ultimately, in the end of the day, a collateral issue that doesn't go to the issues in the

case.

The answer to those questions, I would submit, is no. The study is reliable for the proposition for which it is being used and for which it is being cited. That is three issues.

First, that there are, in fact, cases of low-dose acetaminophen-induced acute liver failure. Two, there is a narrow margin of safety for acetaminophen. Three, that all of the cases in this study, not just the 19, establish this margin of safety, and the defendant has not challenged the rest of the study.

Importantly, Mr. Cohen has indicated that this is the only study out there that suggests that there is a risk at low dose. Of course, this court has been involved in this case for a long time and knows that that is not true.

For example, the FDA scientists who have looked at this question in the Working Group document that Mr. Cohen referred to has indicated that the Larson results reported in this paragraph are identical to those reported by the FDA in its own database.

So, for example, if I can point out to you, in your binder, there is the FDA Working Group

document, which the court is familiar with but may not have focused on this particular paragraph on paragraph number -- on page number 11, where the FDA Working Group --

And it's -- I have a copy if the court --

THE COURT: Is that in this binder, Mr. Tisi?

MR. TISI: It is in this binder. I believe it's the fourth tab.

THE COURT: The one that says, Working Group?

MR. TISI: Yes, correct.

THE COURT: What page?

MR. TISI: If you look at page 11 -- it's actually on page 10. It talks about the recommendation that the dose be lowered to increase the margin of safety --

THE COURT: Right.

MR. TISI: -- for acetaminophen. You -- do you see where I am, Your Honor?

THE COURT: I do.

MR. TISI: Okay. It says, although the acetaminophen manufacturer asserts that the data do not support the assertion that repeated

supratherapeutic ingestion of less than 10 grams a day presents a risk of hepatic injury, the EHRs database -- and that's an FDA database -- and the database of the Acute Liver Failure Study Group show that doses closer to 4 grams a day, the current maximum dose, presents a dose -- a risk in some individuals.

And if you look at the footnote, it indicates the EHRs database and the F -- ALFSG database shows the median daily dose of acetaminophen was 5 to 7.5 grams a day. And that's the median. That's the -- that's midpoint. So some below, and some above.

If you go to the next page, go to -- the FDA Working Group reiterates that point because McNeil, again, said what Mr. Cohen said; the case reports are unreliable evidence for the -- for determining risk.

And the FDA Working Group says, the FDA acknowledges the difficulty in defining a safe daily dose relying on case reports; there are, however, two different databases that suggest toxicity may occur in some people with doses close to 4 grams a day.

So the FDA has indicated that this ALFSG database is reliable because it has been replicated,

not only in their database, but elsewhere.

I would also point out that there are clinical trial data that indicates that at 4 grams, there is an elevated risk of -- of hepatotoxicity.

There are other individual cases, including what the defendant has indicated is not, in the medical literature and which you will see is actually in this group of 19 cases, cases where people were administered acetaminophen in a hospital setting, in a -- in a situation in which the dose is considered to be reliable because it's administered by a doctor, and the person goes on to develop acute liver failure.

So the first thing I would like to say when we start out is that -- is that this evidence, as important as it is, does not stand alone, as Mr. Cohen suggests, but is, in fact, part of a larger -- a larger spectrum of evidence, from animal data to clinical trials to epidemiology observations like this to case reports, that has convinced the scientific and medical community, except for McNeil, that there is a narrow therapeutic margin and a risk at or near 4 grams.

Mr. -- before diving into my argument on this, Mr. Cohen made several startling

characterizations of some of the witnesses in this case. I would start with one to illustrate the point and the point of using snippets, like Mr. Cohen used, to illustrate here.

If you recall, when -- he indicated that Dr. Lee had indicated that there -- this is a safe drug and that there was no risk until you get to close to 10 grams. There was a 2003 article on that. There are multiple articles, from 2003 forward, where Dr. Lee indicated there was a risk at 4 grams.

In fact, if you go to your binder -- I didn't think I was going to have to do this, but if you go to the binder, under the section -- there's a section in which I collected testimony from the various witnesses who have been -- testified in this case on various issues.

And one is on the issue of the risk at 10 grams, and I asked Dr. Lee the following questions. And it's on page 86 of his deposition. Before I get to --

THE COURT: Where are you in the binder?

MR. TISI: It's on the page -- it's in the binder on number 3, risk at less than 10 grams.

THE COURT: Right. Got it.

MR. TISI: And I pulled -- there are --

there is -- this was actually for another purpose that I had this binder made, but there are snippets from the various deposition --

THE COURT: Did you make this for me?

MR. TISI: I did. I did, but it was a -- I didn't intend to use it, frankly. I intended to use it, frankly, with -- in another context.

But there is -- there are pieces of deposition testimony from the various witnesses in this -- behind this binder. But if you go to the one that deals with Dr. Lee, page 86, I asked him the question at line 17: Before I get to discussing the Larson paper specifically --

And my preface question was, I want to talk about your public statements, the things you have published in the past 10 to 15 years on acetaminophen.

Before I get to discussing the Larson paper specifically, let me ask you a global question; in your 20-year work with the federally funded Acute Liver Failure Study Group, have you developed and reported an opinion in the medical literature that some patients with acetaminophen- induced liver failure can occur at 4 grams or less? Yes. Can it occur at 5 grams? Yes. Can it occur at 6 grams?

Yes. And so forth.

And then I asked him the question, on line 11, if anyone were to say that a human being cannot develop acute liver failure until they get to 10 grams a day, is that something that would be consistent with your experience running the largest acute liver failure registry in the world? No.

Are these opinions that you, on behalf of the Acute Liver Failure Study Group, reported to the FDA in a public forum? Yes. And I go through all the opportunities that he had to actually put that out there.

So when Mr. Cohen puts out a 2003 chapter from a medical -- from -- that Dr. Lee wrote and ignores the rest of his published literature for the past 15 years, I think you ought to take note of that.

Let me go -- let me take a big picture here and back up a minute and see where we are and why we're here a year and a half after we started filing the various motions in this case discussing the Acute Liver Failure Study Group.

As this court is aware, there are two big picture questions that deal with the generic issue, not only in the Taylor (ph) case -- excuse

me -- not only in the Hayes (ph) case, but in all of the cases.

Number one, can acetaminophen cause acute liver failure at or near 4 grams either above that dose or below that dose?

Number two, should McNeil have had knowledge of acetaminophen's narrow therapeutic margin such that they should have taken risk reduction measures in the early to mid-2000s, including, among other things, lowering the dose, giving better instructions, redesigning the product to increase the margin of safety?

To answer these two important generic questions at trial, the plaintiffs rely heavily not only on the science but on the consensus of the medical and scientific and regulatory community about acetaminophen.

As both this court and Judge Johnson has noted, it is -- it is the consensus of the medical and scientific community and that McNeil stands squarely outside of that consensus.

In fact, we quoted in our papers the numerous times that Judge Johnson has said that there appears to be a consensus in the medical and scientific community; McNeil just wasn't part of it.

So that's the background, and so we have to understand what it is that the defendant is trying to do here, because the defendant is standing squarely against the FDA, the FDA Working Group, the Acute -- the American Association for the Study of Liver Disease, the American Liver Foundation, the FDA advisory committee votes, and the Acute Liver Failure Study Group.

So what are they doing here, and why are we doing this? Well, they're trying to undo the decades of consensus. McNeil believes that if they can attack this single article, which is of this Acute Liver Failure Study Group, they can illustrate that the rest of the medical community, the rest of the scientific community, and the rest of the regulatory community got it wrong.

In particular, they attack the Larson study. And that -- I -- I assume you have a copy of it, so I won't give you another copy of it, but that article was designed to look at a bunch of things.

It was designed to look at the spectrum of acetaminophen-induced liver failure seen in the first six-years of this NIH-funded registry, from 1998 to 2003.

They didn't just study the 19 cases.

They studied 275 acetaminophen-induced acute liver failure cases. And in that study, they reported about half of the people in the study had attempted to harm themselves by committing suicide.

But the important part of that study is, about half of those patients were trying to get better. They were trying to treat themselves, or their doctors were trying to treat them, for pain.

Now, as part of that spectrum -- and -- and that's why it's important to talk about the big picture here -- they described what they called the low-dose cases, and those are the 19 cases that -- that Mr. Cohen talked to you about.

Now, Mr. Cohen spent a lot of time talking about how medical histories are unreliable and that somehow, the medical and scientific community did not know that there were issues with respect to the reported dosing history of some of these cases.

Frankly, Your Honor, that's an astonishing proposition because it's not true. In the article itself -- and if you go to the article, the page that Mr. Cohen did not cite for you -- on page 1370, in the Discussion section of the paper, they talk about the cases in which people are not

trying to commit suicide.

They say, among -- quote, among the unintentional overdose patients, most reported that they were taking the medication specifically for pain and constitutional symptoms.

It goes on to say -- I'm skipping a couple sentences -- why, then, the sudden onset of severe liver injury? Our data suggests that there is a narrow therapeutic margin and that consistent use of as little as 7.5 grams a day may be hazardous; however, precise information on dosing is often difficult to acquire in some of the patients.

They told the readers of this article that there are some patients -- and I say "some" because, as I will show you, certainly not all -- some patients had difficulty giving and getting a -- a dosing history.

It's not -- it's not surprising that Mr. Cohen would spend his time talking about those some, but there are many other cases in this 19 in which the dosing history was reliable, including the dosing history provided by one of defendants' own experts, unknown to him when he wrote his report.

Dr. Flamm and his medical center provided a case, 010, in which the patient was

described by the -- by the -- by their institution as having acetaminophen-induced liver failure, and Dr. Flamm personally confirmed the low dose.

So while the defendant has spent a lot of time talking about how unreliable this is and picking apart little parts of the paper, not only did the authors disclose that there was a problem with some patients, they didn't talk about -- fairly talk about the -- the breadth of the cases, of the 19 cases.

Now, I want to emphasize before I really get into the argument in this case that this 2005 article is one of the lines of evidence that the FDA, the ASLD, and the FDA Working Group relied on to recommend that there be better instructions for acetaminophen, that the dose be lowered, that the margin of safety is too small, and that there is a risk with this problem -- with this drug.

Now, to -- to -- having set up where this argument fits in in the -- in -- in -- in the spectrum of this case, now I want to turn to what McNeil's attacks are and how this issue unfolded so that we're here in early 2016 talking about this instead of something that happened a long time ago.

To support its attack on this peer-

reviewed article, McNeil has procedurally collected all the CRFs for the Larson study. They could have focused on all of them, but they didn't. They chose to focus on the 19.

THE COURT: Is it a problem with the methodology that the authors of the report acknowledge that they didn't look at the CRFs?

MR. TISI: No, because this is -- if you look at the paper, Your Honor, the paper has something in the range of, I think, 11 authors. Each of them do a part of the paper.

Dr. Lee was involved in actually looking at the CRFs, and he testified to that. Dr. -- Dr. Larson was -- her job was to take the information that was in the spreadsheet that was provided as a result of this process and collate it and -- and -- and write a first draft.

The important thing about the methodology, Your Honor -- and Dr. Robuck testified to this extensively, and it's in her declaration -- the procedures for collecting and analyzing the data were not set up by the Acute Liver Failure Study Group in a vacuum.

These were set up in connection with the National Institutes of Health, which not only

approved and reapproved and reapproved the grant for the -- for the Acute Liver Failure Study Group, but the practices, including the Manuals for Operation, including the data collection, including all of that -- was approved by the F -- by -- by the National Institutes of Health.

They had monthly steering committee meetings, where -- Dr. Robuck sat in on those steering committees, and these cases were -- were presented and discussed, and any issues related to the conduct of the Acute Liver Failure Study Group were -- were conducted.

They had a once-a-year meeting of all the investigators. And during the course of this, any issues related to data collection were -- were -- discussed.

She testified that the low-dose cases were specifically discussed, not only within -- within the -- within the ASLD themselves, but with the NIH, and they were provided with summaries of these patients.

She took those patients and went back to what's called a data safety monitoring board, which is an internal board -- it's described in her declaration -- with the NIH. Dr. Lee and none of the

investigators were part of that.

The summaries of these patients were provided so that any information, any problems with data collection, with patient safety, with any conduct of this study over the -- the almost 20 years it's been -- it's been in effect, would be identified by the -- by the data safety monitoring board and be brought back to the Acute Liver Failure Study Group and corrected.

And so while Mr. Cohen has spent a lot of time taking apart individual cases, the truth of the matter is, the methodology that was used by the Acute Liver Failure Study Group was unique to almost any study that I've been involved with in the years that I've been doing this, in that it was scrupulously supervised by the National Institutes of Health, its procedures were subject to peer review, its procedures and -- were subject to renewal every three to five years, and it passed every single time.

In fact, Dr. Robuck -- I believe her last question and answer in her deposition was, have you ever seen a study that was more meticulously done, even if there were flaws in various -- as will inevitably happen in 20 years, that there would be things missing in forms and those kinds of things,

but when you look at the conduct of the study, how does it compare? And he (sic) said -- both Dr. Lee and this study were remarkable in -- in their contribution to the understanding of this -- of this disease.

So to answer your question directly, Your Honor, there were checks and balances for the methodology that was employed for this study, the data collection, the data analysis, and that was provided by the National Institutes of Health.

So what happened in this case -- and I -- I believe -- returning to my argument, what I think we have to do is go back to where we were in January.

The defendants produced a report. The report's from three experts; a Dr. Brown, a Dr. Flamm, and a Dr. Brent (ph). Importantly, and as I'll discuss in a moment, none of these three litigation experts have ever focused their research activities on acetaminophen, on acute liver failure related to any drug.

They're -- even though two of them were members of the Acute Liver Failure Study Group, remember, the Acute Liver Failure Study Group does a lot of things other than study drugs. That was their

focus. They weren't studying acetaminophen.

But they come marching into this courtroom in January with reports that say four things, and we can't forget those four things because it calls into question the methodology that they used to analyze these cases.

They said, number one, many of these cases didn't even have acute liver failure; they had things like sepsis or shock or some other things; many of them didn't even have acute liver failure.

Number two, they said, well, if they had acute liver failure, they must have been due to other things other than acetaminophen. They mentioned things like hepatitis A. They mentioned things like alcoholic liver disease or cirrhosis.

Number three, they say, well, in the few cases that were actually acute liver failures -- acute liver failure and in those even fewer cases that were due to acetaminophen, not one, not a single one was a case that can qualify as low dose.

And they further argue, even though one of them was listed as a participant in the study and the other one, in fact, participated in the study, said the article ought to be retracted and should not be -- should not have been published in the first

place.

Now, over the past two months, we have provided declarations to the court of the following people so the court understands and the record is clear as to who they are.

William Lee is the private investigator -- the principal investigator for 20 years for the Acute Liver Failure Study Group and the holder of the NIH grant and the senior author of the Larson study. He's authored close to 150 articles on acute liver failure and acetaminophen toxicity. He was not retained or paid a dime.

Anne Larson was the site investigator and lead author for the Larson article. She's published over 30 articles on acetaminophen-induced liver failure. She has not been paid a dime.

Dr. Robuck, the NIH fund official in charge of the NH- -- Acute Liver Failure Study Group grant, she was not retained and has not been paid a dime.

I emphasize this to note that these willing -- that these patients -- that these doctors were willing to come forward at -- at -- at tremendous time and on short notice to provide the declarations that are before the court.

In addition, we provided the reports of Dr. Kaplowitz, who was the acute -- who is widely considered one of the nation's authorities on -- in this area and published a textbook on -- on drug-induced liver disease; Dr. Davern, who was a site investigator and author on the -- on the Larson paper, and two toxicologists.

I go through this because I think you need to understand -- sometimes I watch on television people debating issues, and sometimes it is important to understand where they stand in the medical and scientific community because not all opinions are equal.

I have provided in your book as tab 1 a chart that we put together, and I'd just like to take a moment and go through them, because I think -- against the backdrop of the argument you just heard, I think you need to see where these experts line up.

Publications on -- on acetaminophen, acute liver failure, and drug-induced liver injury, Dr. Lee, 152 articles; Dr. Kaplowitz, 88; Dr. Davern, 34, Dr. Larson, 36.

Dr. Brown has had six, and Dr. Flamm has had one. And they go through each of these article -- each of these on -- reports of acute liver

failure, acetaminophen. These are not -- respectfully, while they may be -- while they may be experts in the fields in which they are -- hepatitis and other areas, liver transplants, they are not experts in the field of drug-induced liver disease or of acetaminophen-induced liver failure.

In fact, just to illustrate the point, Dr. Flamm himself was asked to write -- author a book on liver disease. Interestingly -- and it's tabbed in your book -- the person he asked to write the chapter on drug-induced liver disease was Dr. Davern.

So now, what do these qualified experts and witnesses say? You've heard nothing from Mr. Cohen about the analysis performed by any of these witnesses.

McNeil's experts failed to consider important evidence when they drafted their report, including the presence of acetaminophen adducts that was subsequently performed on these low-dose cases. I think Your Honor cued into that in one of the questions you asked Mr. Cohen.

If you turn to the Lee declaration, page 14 and 15, he describes the importance of acetaminophen adducts. And I have a copy if Your Honor needs it. But on pages 14 or -- and 15 --

THE COURT: Hang on.

MR. TISI: -- he talks about having received the expert reports of Drs. Brown and Dr. Flamm and Dr. Brent (ph), and as a scientist, he was concerned; did I get it wrong?

And one of the things he did was go back and look and see -- you know, we have this new test that we had done for acetaminophen toxicity; we know these patients had toxicity -- we know these patients had acute liver failure; did we, in connection with another study we had done -- and there were several studies -- actually test these patients for acetaminophen adducts? In fact, they had.

That would be the first question that a -- that an expert who was looking at things in an unbiased fashion would ask. It's the question that I would have expected Dr. Flamm and Dr. Brown, who were members at one point of the Acute Liver Failure Study Group, to have asked; by the way, McNeil, are there adducts levels on these patients, and can you get them for me, because I'm about to write a report that says some of these patients don't even have acetaminophen toxicity.

Now, it's important to understand what these adduct levels -- because I suspect you're going

to hear from Mr. Cohen about what these adduct levels show and what they don't show.

If you go back to the chart that I provided to you about the publications of the various experts in this case, you will learn that plaintiffs' experts and Dr. Lee and Dr. Larson have published on acetaminophen adducts. They are the primary publishers of this issue -- on this issue and what they mean.

Defendants' experts have not published a single article or have ever given a talk, to my knowledge, about acetaminophen -- acetaminophen adducts.

Dr. Lee testified in his deposition -- and it was very clear -- that the presence of adducts only shows you that there is acetaminophen toxicity. It tells you nothing about how much -- how -- the dose that the patient took. I suspect you're going to hear Mr. Cohen get up and say, oh, by the way, these high adducts correlate with high dose. They don't.

The other thing, interestingly, that -- that these experts say -- point out is, well, why didn't the defendant ask about genetic polymorphisms? As you see from Dr. -- Dr. Lee's declaration, many of

these same patients were subject to genetic testing to see whether there were common -- common genetic features which would explain why patients developed acute liver failure at low doses.

And, lo and behold, in a patient called Kort (ph), patients -- they studied 6 grams or less, but -- but the 4-gram patients were in that group -- showed a common genetic polymorphism which would explain -- which would help to explain why some people get risk and the other people don't.

The fact that McNeil's experts never sought that data or -- and, as experts, didn't even care to ask for it says a lot about the analysis that's before you.

They failed to consider the fact -- and this is something that Dr. Flamm didn't realize until Dr. Lee pointed it out to him, that one of the low-dose cases was actually confirmed by his site and that Dr. Flamm confirmed the dose.

They failed in their reports to discuss that which they had made a big deal previously, that it didn't exist, that there was no patient in any United States hospital that ever got acetaminophen under the supervision of a doctor who got acute liver failure at 4 grams or less. There was such a case in

these 19.

So against the backdrop, not only must you consider what the acute liver failure authors say, you have to consider the source of an -- not only -- the quality of the expert reports that are put before you to challenge that.

So the court will have to decide in this Daubert hearing not only whether the Daubert challenge has a basis and (sic) whether, ultimately, any of the data that you hear in this case goes to -- to the jury.

So with that as a background, I'm now going to shift a little bit to talk about the big picture, the big picture of where -- defendants' analysis of the Acute Liver Failure Study Group article and the article itself, what it says, and whether it even makes a difference.

First of all, I'd like to point out that under Daubert, peer review is not necessary, but when it exists, it's a very important indicia of reliability. The reliability is even higher, and the courts presume it's even higher, when the study is done independent of and prior to litigation. And it's at its highest when regulatory authorities like the FDA or the NIH rely on the study.

And even though I couldn't find a case that says what I'm about to say, I would submit that the reliability is even higher when the study is not only relied on by the FDA and the federal government but is funded by it and is peer-reviewed by it.

And I will emphasize that Dr. Robuck indicated that this study was submitted to the FDA prior -- was submitted to the National Institutes of Health prior to it being published, and nobody said, you know, I'd like to see the methodology for these low-dose cases. Nobody said, you know, this doesn't make any sense; we'd like to see the -- the case report forms. Nobody said that this -- this doesn't jive with the medical and scientific literature that is already out there in the medical community.

I'd like to point out that no -- no questions were ever raised until this past six months on this study, not the NIH, not the FDA, not the Journal of Hepatology; importantly, not Dr. Brown, not Dr. Flamm, who were part of the Acute Liver Failure Study Group and could have done so at any time.

Nobody suggested that they do this so-called body burden calculation that they -- that's woven throughout all their reports and we'll talk

about in a moment.

Yet they claim that this process was flawed, and their experts never sought to explore the process.

Now, I really want to talk about Dr. Brown, why this is so -- why what's going on in this courtroom has not played out in the medical and scientific community, and I'm going to give you two examples.

In tab 3 of your binder is a series of emails that were produced in Dr. Davern's deposition, and they're ones that the court has not yet seen but I think is telling and illustrates as to what a farce this proceeding has become.

In your binder, Dr. Brown was asked -- as you recall from the papers that we filed, Dr. Brown was asked to resign from the Acute Liver Failure Study Group in the mid-2000s because of his inattention to the group, his failure to enroll cases, his failure to employ the proper paperwork.

Nevertheless, because he had been -- and this is before any of this issue came up. Before he had been an -- because he had been an investigator in the past, Dr. Lee, on behalf of the Acute Liver Failure Study Group, asked Dr. Brown to participate

in a new study, a five-year retrospective analysis of Acute Liver Failure Study Group cases.

That happened in 2015, while acting as McNeil's expert. And you'll see that there are two emails there. There's one in 2016 and 2015.

Importantly, this publication included a subanalysis of over a hundred acetaminophen-induced acute liver failure study groups in the Acute Liver Failure Group registry.

You will see in there a March 29, 2016 email from Dr. Brown, two months to the day after he filed his expert report in this courtroom, saying that the Acute Liver Failure Study Group doesn't know how to analyze an acute -- doesn't know how to look at a case of acute liver failure, doesn't know how to -- you know is sloppy in its analysis of acute liver failure related to acetaminophen, and he puts his name on a paper that is going to be published -- or has been published relating to the analysis of Acute Liver Failure Study Group and acetaminophen. It doesn't talk about dose issues, but it talks about the first two issues we talked about before.

Because if you recall, Your Honor, before, the initial report of Dr. Brown is, these patients don't even have acute liver failure, and if

they have acute liver failure, it's probably not due to acetaminophen.

Yet Dr. Brown, outside the courtroom, is putting his name to an article by the Acute Liver Failure Study Group as now marching into this court saying that these guys don't know how to do anything, and they're unreliable.

Now, if you take away anything from the Daubert -- from the Daubert standard, it's that experts are supposed to employ the very same methodology in the courtroom that they apply in their daily life as a scientist and as a doctor. I question whether or not Dr. Brown meets that standard.

I'll bring another point --

THE COURT: Mr. Tisi, in this tab, there's a March 29, 2016 email. It looks to be from Dr. Brown. He says, I added my comments. Are those comments then on the attached text?

MR. TISI: Yes, they are -- they are -- they are on the attached.

THE COURT: Okay.

MR. TISI: In other words, he's -- he's -- he's giving approval to the study and not saying -- you know, in that email, there's nothing

that says, you know, wait a second; I've just been involved in a proceeding and I wrote a report two months earlier where we have a real problem with -- with -- with the Acute Liver Failure Study Group's methodology; I'd like to see the case report forms.

You would think -- I mean, if I was -- if I had a law clerk who wrote a bad memo for me on -- on January 30th and I get a new memo on the same topic on March -- on March 30th, I'd say, I'd really like to see the data upon which you -- which you rely. Dr. Brown didn't do that.

I'm going to give you another example as to why this is a -- a difficult argument for the defendants to make. Exhibit Number 21 to our motion is case 12. It's patient 010, which is Dr. Flamm's patient.

In his January 29th report, Dr. Flamm analyzed the 19 cases. It included an analysis of patient 12. In his report, he said the cause should not be listed as acetaminophen and that the dose is unreliable. And, further, he said it would be unreliable for anyone -- anyone on -- any reasonable scientist to describe this as a low-dose case.

But unbeknownst to Dr. Flamm when he wrote his report and as described in Dr. Lee's

declaration at page 10, 11 and page 34 and 37, this was a report -- this was a report of a case out of Dr. Flamm's -- out of Dr. Flamm's site. His site contributed the case.

His site, and maybe even him, said it was acetaminophen-induced liver failure. His site described a biopsy as consistent with drug-induced liver disease. And as we learned, as you see as attached to Exhibit 7 to his -- to Dr. Lee's declaration, Dr. Flamm himself confirmed the dose as less than 4 grams.

Now, you saw Mr. -- Mr. Cohen -- I -- I thought it was interesting that Mr. Cohen brought up the important parts of this form, and I -- and I wish I could ask him to bring up that part. And he said there was several -- I don't know if you'll recall that he said there was several important parts of the form I want you to focus on.

I thought it was interesting that one part of the form he didn't focus on -- and all of these reports --

And if I can -- I only have one copy, and if I can, I will give you my copy of Dr. Flamm's report. May I approach, Your Honor?

THE COURT: Yes.

MR. TISI: This is Exhibit 12 out of the binder. And if I could argue from this for a moment because I only have one copy?

THE COURT: Sure.

MR. TISI: You will notice that there is a -- it has two forms. Each of these consist of two forms. There's an admission to the study form and an outcome form. One is filled when the patient is enrolled, and the other one is admitted when -- after the patient is analyzed.

And there is a section -- give me -- bear with me a moment.

I'll have to find it, Your Honor. It's the final diagnosis of a patient. I have another form here (indiscernible).

THE COURT: Thanks.

MR. TISI: It's where the medical doctor indicates what the -- what the final diagnosis of the patient is, and it indicates on this case that the patient -- it's a little box, and they fill it in. It says, acetaminophen. It doesn't say indeterminate. It doesn't say idiopathic. Their site, Dr. Flamm's site, said this was acetaminophen-related.

And, of course, we also know that

they -- that the -- that in realtime, in real science, Dr. Flamm and his colleagues were correct.

How do we know that? Well, we know that because if you go to table 1 of Dr. Lee's declaration, this patient was adduct-positive. The patient had the presence of acetaminophen adducts.

So Dr. Flamm -- and the reason for me bringing you -- bringing this up to you is that Dr. Flamm, in his litigation report, says, there's no way that this could possibly be acute liver failure due to acetaminophen; nobody would ever say that; the dose is unreliable, and we come to learn that his site made the conclusion that it was acetaminophen, we know the adducts were positive, and Dr. Flamm confirmed the dose.

So let's talk about the issues in the case. First of all, defendants filed on Friday issue one; should you strike the declaration of Dr. Lee? That issue wasn't raised by Mr. Cohen. If -- do you want me to find that portion of the -- of the -- of that form? Would that help?

Okay. Number one, should you strike the declaration of Dr. Lee? McNeil filed a motion last Friday to strike the Lee declaration. We filed our opposition yesterday. I just want to discuss it very

briefly --

THE COURT: Okay.

MR. TISI: -- because I think it is important.

Respectfully, it is a bizarre request. The law encourages lawyers such as myself to thoroughly investigate and do exactly what I did. When we had the motion that was filed, we contacted the lawyers for Dr. Lee. We sent Dr. Lee, through his counsel, the reports of Drs. Brown, Flamm, and Brent (ph) and the -- and the -- and the motion that was filed on behalf of Dr. -- on behalf of McNeil.

They were read by Dr. Lee before I ever had a chance to meet with him. I met with him in mid-February. He did most of the talking. He -- he gave us the information. We took the information down. We turned around a declaration. We sent it to his lawyers. Drafts went back and forth, and he signed the -- he signed it.

I will point out that McNeil did exactly the same thing with the declaration that it provided in January. It drafted the report. It drafted the declarations, sent it to the lawyers, had it signed, and it was submitted to the court.

So I would argue that the motion they

filed on Friday is not only frivolous but is designed to get the court not to look at the substance of it.

There are, however, two corrections that Dr. Lee made in his deposition, so I -- I want to call it to the court's attention.

In paragraph 14, he used the word "median" instead of "mean" when describing the median dose being 7.5 grams in the Larson study.

The second is paragraph 41, which was left in by accident. He testified to that.

As to the remainder of the 48-page, single-spaced declaration, it remains his opinion as of today.

Issue number two; does the fact that there is 17 reported cases, and if there are 16 or 17 or 18 cases that remain after the reanalysis, based upon what we now know, does it make a difference?

It really doesn't. The point in describing the low-dose cases was not to give a conclusion as to causation but to describe the low-dose phenomenon in the Acute Liver Failure Study Group data. It's a descriptive paper. It fits into all of the other articles that are out there in the peer-reviewed public's literature.

There is a statement in the article that

indicates -- that they can use at trial that says some of the patients can have a difficulty giving medical history -- giving dosing history. But some don't.

But there are also reasons why some of the patients in this -- in the dosing -- in this group are reliable. One would be case number 9, that's described in Dr. Lee's declaration, ending in also 010.

And -- and I just want to be clear, there are -- even though we can't use the prefix for these studies under the agreement with the Acute Liver Failure Study Group -- they're giving patient identifying information -- and -- and just coincidentally, the case that Dr. Flamm has, which is case number 12, ends in 010. Case number 9 from another institution ends in 010. They're two different cases, just so that -- it may be confusing, but -- but you can see that there.

THE COURT: I see it.

MR. TISI: That case is a case -- as I indicated, is a hospitalization case where the patient got 12.5 grams over five days. If the patient was -- was being given acetaminophen in a hospital setting, they would have gotten no more than

4 grams a day, which fits exactly the pattern of being in the hospital for five days.

So what remains after this study is, if you substituted the -- the -- the number 17 or 16 for 19 -- is, you still have a description of acute liver failure with patients who took 4 grams or less.

It is not what the defendants came marching into court with in January, which is, not a single one of these patients are reliable; not a single one -- most of these patients don't even have acute liver failure or acetaminophen-induced liver disease. That argument is, apparently, out the window because of the adducts testing.

So now they're focused on a handful of cases, and the question is, does it make a difference? I question -- and I raise this because if the study had written, for the purposes of the jury and purposes of reliability -- if the jury had heard that there was 17 cases or 16 cases of acute liver failure at less than or equal to 4 grams, the -- the -- the observation would be exactly the same.

Now, I want to go to number three, a third issue; what do the acetaminophen adducts show? Now, in the reports, McNeil's experts, as -- as we

had indicated, indicate not only was the dose unreliable, but these patients don't even have acute liver failure. I think -- as I indicated, I think that's kind of out the window now.

Table 1 of the Lee declaration on page 15 indicates that for the acetaminophen patients who were tested, 18 of them, 18 of the 19, 16 were adduct-positive. One of those patients was tested too long after the patient had been exposed, so the adduct test would be unreliable. So that there was only one patient, which happens to be the Macrobid case that Mr. Cohen talked to you about, that was -- should not be included.

While these -- while this test is not commercially available, they are the smoking gun to show acetaminophen was a cause of acute liver failure in these patients, but this shows nothing about dose.

It shows that the Acute Liver Failure Study Group investigators were largely right in their non-litigation study, and McNeil experts were mostly wrong in their litigation reports.

That is a really important point here, Your Honor. They came marching in here in January saying -- saying that, based upon their -- their post hoc analysis of these cases, that these cases weren't

even acute liver failure or related to acetaminophen.

The acute liver failure -- and it indicates why there is an indicia of reliability accorded to studies like this and a skepticism of post-study analysis like that done by the Acute -- by -- by McNeil's experts.

THE COURT: Let's wrap it up, Mr. Tisi.

MR. TISI: Okay. In your binder, there is a -- there is a quote from Dr. Lee on page 21, and I asked him, if anyone were to stand up in court and say the presence of acetaminophen adducts tells you anything about dose, would that be true? The answer is no.

Let's talk about this half life issue because it involves our -- our request that these experts be struck.

In their reports, McNeil's reports rely on a formula, and the formula is basically this: Measure the acetaminophen in the person's body at the time that the person presents; look at their blood; assume a half life of that patient; calculate backwards; and through this, you can calculate and demonstrate that the dosing history given by the patient is incorrect .

The problem with that -- that -- that

hypothetical calculation is -- is several. Number one, it doesn't -- it doesn't describe the phenomenon that as a patient is in acute liver failure, they continue to -- and if they're taking acetaminophen, it continues to accumulate in the liver. It's not excreted. So it gives a high level -- an inappropriately high level.

It is also important to note that not only does the plaintiffs' experts -- not only does Dr. Lee and Dr. Larson -- but defendants' own experts agree that that test has never been validated in a -- in a situation involving acetaminophen.

So, for example, Dr. Flamm, as indicated in his deposition on page 107 and 108 --

Well, we asked this of Dr. Brent (ph). From your bibliography, are there any articles that this estimated body burden -- the way you did it in your supplemental report? And the answer, from acetaminophen? Yes. No.

We asked Dr. Flamm, there is -- question on page 286: There is no study that says -- question: Is there a study that says that if we combine body burden with an estimated half life, we can determine whether a dose reported in a patient in a chronic dosing situation is accurate; that has

never been proven or attempted to be proven, true?
Answer: There is no such study.

Dr. Lee agrees. Dr. Kaplowitz agrees. Dr. Davern agrees. Everybody agrees that this is not a formula that has ever been validated in the realm of science in any study that will demonstrate the -- that -- that dose.

And I would point out that Dr. Brown, Dr. Flamm has never recommended that the -- that the Acute Liver Failure Study Group employ such a -- such a thing.

And I would also point out, in reality, that the FDA has been struggling with the issue of confirming dose for 15 years. You would think that in that time, McNeil would have come forward and said, you know something; FDA, we found the Holy Grail; we have a -- we have a -- a formula that all you have to do is plug in a couple numbers, and we can demonstrate that all this concern about low-dose ingestion and margin of safety is a bunch of -- is a bunch of hooey.

They never did that, but they march into court and put a declaration before Your Honor, put a -- put a -- put a -- a report before Your Honor that says -- that says that they've never published

on it, and we're supposed to -- we're supposed to allow them to present that under the guise of science.

So we would ask not only that that be struck as unreliable and -- and -- and contravening Mr. -- Dr. Lee and -- and everybody else, but their experts be struck -- struck on that.

The truth is this, Your Honor, and -- and -- and -- and it is difficult, and this I agree with Mr. Cohen on. It's difficult to discuss each and every one of these cases.

But I did ask Dr. -- I did go through these -- these cases on Friday with Dr. Larson, and I said, Dr. Larson, we can't go through each one of these individually, but let's -- let me ask you this as a -- as a --

And I can provide you with this testimony. And I did this with Dr. Lee as well.

-- let me ask you in the spectrum, are there cases in the 19 in which the dosing history was more challenging? Yes. Are there cases within the 19 where the dosing history was less challenging? Yes. Is that to be expected? Yes, it's to be expected because patients -- because doctors sometimes find that patients can give accurate

histories, and sometimes they don't, but we accepted the patients' history, and we described what we saw. Does that mean that there's not contradictory information for some of them? Of course, there is. But does that mean that the results of the study is -- are wrong as reported? Of course not.

The defendant has a lot of arguments that it can make at trial that dosing history is sometimes difficult. I expect that that's going to be a major thrust of their -- of their argument.

That has never been in dispute. Dr. -- Dr. Lee and Dr. Larson include that -- admit that freely. It's in their declaration. It's -- it's throughout the medical literature.

Does that mean dosing history is unreliable? Sometimes it may be; sometimes it may not be. They were reporting what they saw. And that's what this paper is about, and that's why it's an important paper. It fits in the -- in the spectrum of cases out there.

I'm going to wrap up now. We've talked about -- I just wanted to wrap in here that we have a challenge to the defendants' experts. I think they went out way on a limb, way beyond where an expert ought to be. They became advocates in this case, and

I believe that they -- that they should be struck for the reasons in our motion.

I would point out, Your Honor, that sometimes enough is enough. We've been through this for about a year and a half. We've argued every single issue that you could possibly have. This is the time to put an end to this constant wrangling about what the data mean and allow the parties to put their evidence, put their proofs before a jury, and the Larson paper's one of them.

Thank you very much.

THE COURT: Thank you, Mr. Tisi.

All right. We're going to break.

Do you have something else you want to argue Mr. Cohen?

MR. COHEN: I wanted to respond. Two minutes.

THE COURT: All right. You have two minutes.

MR. COHEN: Thank you, Your Honor, very much.

You know, there's an old -- a movie about handling the truth. Well, I'm going to say that about the dose. This is all about dose, and the plaintiffs can't handle the dose.

The adduct data, as Mr. Tisi correctly said, does not establish that these are low-dose cases. Their own experts all admitted that. Dr. Lee admitted that. Dr. Larson admitted that. All of their experts have admitted that. The low -- the high adduct data does not establish that any of these cases occurred at low dose.

And it gets worse, Your Honor. Do you remember the movie "A Christmas Story," where the mother says, Ralphie, you're not going to get that BB gun for Christmas because you're going to shoot your eye out?

I think this gun has misfired. If we could put up (indiscernible), the 2011 study published by the ALFSG with Dr. Larson as a coauthor, Dr. Lee as the primary author, here's what it says: 1.0 nanomoles of adducts indicate a definite acetaminophen overdose.

They didn't put that in the declarations they submitted, and then they learned this at our expert's depositions that, oh -- oh, my God; the gun misfired. The smoking gun we just heard about, it misfired. All their adduct levels are between 3 and 41 nanomoles per milliliter.

I invite you to look at the very table

Mr. Tisi just put before you. They wrote that, and they published that. And that's the Acute Liver Failure Study Group, and that is why the adduct data now, we're being told, doesn't establish dose. Oh. Oops. It establishes overdose. They don't want you to know that.

THE COURT: And do I have that article?

MR. COHEN: May I approach?

THE COURT: Thank you. Thank you.

MR. COHEN: One last thing. They -- they talked a lot about Dr. Brown. They brought your attention to Dr. Brown's emails. They were offered Dr. Brown's deposition. They declined. Dr. Brown's not here to explain his emails. I would ask the court not to consider that evidence as -- as anything other than hearsay and unrelated.

Finally, Mr. Tisi talked about polymorphism. Dr. Lee testified that his papers on genetic testing contain no data about 4 grams or less ingestion of acetaminophen at page 322 of his deposition, lines 3 through 7; we didn't discuss the quantities in the papers -- two papers.

Finally, Your Honor, it is a problem, the methodology used for a study that the plaintiffs' experts are relying on, and it's a bigger problem

when the authors of that paper actually excluded the cases in 2009 and didn't tell the scientific community and didn't tell this court.

Thank you.

THE COURT: Thank you, Mr. Cohen.

Mr. Tisi, you may have your case report back.

MR. TISI: Okay.

THE COURT: Thank you very much --

MR. TISI: Can I make one --

THE COURT: -- for your written submissions.

MR. TISI: Can I make one point about this case report, Your Honor, because I think it is -- it is -- Mr. -- Mr. -- with your indulgence, about 30 seconds?

THE COURT: Okay.

MR. TISI: I asked -- and it's in your binder -- about this adduct issue of the -- this -- this backfiring smoking gun issue. Every single witness said, it measures toxicity; it doesn't measure dose.

But to illustrate that point, I would go to the case 010, which is number 12.

THE COURT: Um-hmm.

MR. TISI: And that case, as we know, is a 4-gram case because it was in a hospital. That patient had a -- a 9. And if that patient had a 9 adduct level, it does -- it would demonstrate that patient had a normal dose and had a 9. That demonstrates that -- that this measures toxicity but doesn't measure dose, as Mr. Cohen just told you.

Thank you very much, Your Honor.

THE COURT: Thank you.

MR. COHEN: Your Honor, one housekeeping matter?

THE COURT: Yes.

MR. TISI: We do have the graphics printed out.

THE COURT: Okay.

MR. COHEN: Do you just want a set?

INDISCERNIBLE SPEAKER: Could I have a set?

MR. COHEN: Yes.

INDISCERNIBLE SPEAKER: Thank you.

THE COURT: Could I see Ms. Jones and Mr. Tisi for just a moment back in chambers?

ESR OPERATOR: All rise.

(Whereupon, the proceeding was concluded at 12:23 p.m.)

C E R T I F I C A T I O N

I, Judi Y. Olsen, Registered Professional Reporter, do hereby certify that the foregoing is a true and correct transcript from the electronic sound recordings of the proceedings in the above-captioned matter.

April 29, 2016
Date

Judi Y. Olsen, RPR

A

AASLD 21:15 23:16
aberration 45:8
ability 7:4
able 4:15 8:1 22:13 23:12,21
above-captioned 101:8
abstract 13:8 36:15
accept 50:2 51:7
acceptable 44:13
accepted 41:17 95:1
accident 87:10
accommodate 8:1
accorded 91:4
accumulate 92:5
accurate 92:25 94:25
accurately 8:18
acetaminophen 1:4 12:7 13:4,14 14:1 14:5,12,24 15:2,8 15:20 17:5,20 18:2,8 19:1,4,4,17 20:6,10,24 21:6 21:22 22:1 26:6 27:1,2,6,10,11,18 29:23 30:17,18 32:11 34:21,25 36:4,6,13,17 37:6 37:18 38:1,15 39:2,8,13,24 40:2 40:4,6,10 41:23 50:13,23 51:9,11 54:9 55:20,24 56:10 57:9 59:17 59:23 61:3,17 65:16 69:20 70:1 70:13,19 71:11 72:19 73:1,18,24 74:8,13,23 75:7 75:12,12,16 76:23 80:17,20 81:2 82:20 84:21 85:6 85:11,13 88:24 89:24 90:6,16 91:1,11,19 92:4 92:12,19 97:18 98:20
acetaminophen's 61:7
acetaminophen-i... 54:7 62:22 63:1 65:2 71:15 73:6 80:7 83:6 89:11
acetaminophen-r... 84:24
acknowledge 66:7
acknowledges 18:6 22:2 56:20
acquire 64:12
acting 80:3
activities 69:20
actual 12:11
acute 6:15,19 7:7 12:4,7 14:6,11,15 18:8 33:13 51:8 54:7 56:4 57:12 59:20 60:4,7,9,22 61:4 62:5,7,13 63:1 66:22 67:2 67:11 68:8,13 69:20,23,24 70:8 70:10,12,17,18 71:8,11,18 72:2 72:20,25 74:10,18 76:4,24 77:3,15 78:20 79:17,24 80:2,8,8,13,14,15 80:16,20,25 81:1 81:4 82:4 85:10 87:21 88:12 89:5 89:11,19 90:2,16 90:18 91:1,2,5 92:3 93:10 98:2
add 9:22
added 81:18
addition 72:1
additional 8:17 24:24 27:7 52:5
address 4:9 15:19
adduct 33:17,19 74:25 75:1 90:10 97:1,6,23 98:3 99:19 100:4
adducts 34:4,7 73:18,24 74:13,20 75:7,13,15,20 85:6,14 89:13,24 91:11 97:17
adduct-positive 85:5 90:8
administered 57:9 57:11
admission 51:18 84:7
admit 42:14 95:12
admits 31:14 38:2 42:2
admitted 3:13 48:16 51:19 84:9 97:3,4,4,5
advisory 15:3 20:23 21:5 23:12 45:15 62:7
advocates 95:25
age 41:12
agencies 45:1
agenda 4:3
agent 33:12
ago 19:20 22:12 24:4 27:18 38:22 65:24
agree 17:18 92:11 94:9
agreed 17:1 35:12
agreeing 52:15
agreement 88:12
agrees 93:3,3,4,4
Ah 40:16
alcohol 26:16 34:14 35:25 36:25
alcoholic 70:15
ALF 14:13 15:7,21 17:7,16,22 18:12 19:1 39:2,12,25 43:20 50:24
ALFSG 12:18 13:13 14:14 15:10 15:14,16,19,22 16:6,8,12,15,19 16:21 17:3,8,15 18:17,24 19:9 23:3 24:2,8 25:13 25:13,23 26:12 42:10,12 43:6,20 44:22 45:15 46:21 47:24 48:5,25,25 49:2,4 50:24 51:6 56:9,24 97:15
allow 53:15 94:2 96:8
allowed 42:15,16
ALT 40:3
altered 26:13 35:22
alternative 33:24
Alyson 2:5 9:17
Alyssa 53:9
amass 52:19
ambiguities 24:25
American 21:14 62:5,6
amount 8:20 50:8
amounts 50:2
analyses 30:10
analysis 69:9 73:14 76:13 77:15 80:1 80:16,19 82:18 90:25 91:5
analytical 17:9 51:5
analyze 51:10 70:6 80:14
analyzed 82:18 84:10
analyzing 66:21
Angeles 37:6
animal 57:18
Anne 71:13
annotated 20:4
annual 21:16 23:16
answer 12:10 17:5 17:15,20 22:21 28:6 30:24 35:8 38:25 39:2 41:12 42:15,25 43:2,7 44:3 45:5 49:1,10 51:2,4 54:2 61:13 68:21 69:6 91:12 92:18 93:2
answered 18:4
answers 48:7
antibacterial 33:12
anybody 49:3
apart 65:6 68:11
apparently 89:12
appear 48:7
APPEARANCES 1:9 2:1
appears 61:24
applies 52:4
apply 81:11
approach 11:18 32:3 83:24 98:8
appropriate 44:4
approval 81:24
approved 44:22 67:1,5
April 1:5 101:13
area 72:4
areas 73:4
argue 10:12,15 11:11 70:21 84:2 86:25 96:15
argued 96:5
argument 3:3 7:8 7:22 10:23 53:5 57:24 65:12,20 69:12 72:17 82:13 89:12 95:10
arguments 6:23 95:7
article 14:10 19:9 19:24 20:5,9,15 20:18 23:6,9 31:11 58:8 62:12 62:20 63:22,22 64:13 65:13 66:1 70:24 71:14 72:25 75:11 77:16,16 81:4 87:25 98:7
articles 20:17 58:9

71:10,15 72:21 87:23 92:16
ASHCRAFT 1:17
asked 7:9,11,12,14 15:17 16:2,24 18:10 19:18,19,23 20:12,24 21:2,10 22:6,17 23:13 25:10 34:23 35:3 37:9,12 38:4,17 38:19 43:14 47:5 47:8,14,23 48:4 48:11 53:21 58:18 59:11 60:2 73:8 73:10,21 74:19 79:15,17,25 91:10 92:15,20 99:18
asking 48:3,4
ASLD 65:14 67:19
assertion 55:25
asserts 55:24
assessment 12:12
assigned 40:2
assigning 39:24 41:23
assist 12:12
association 18:7,12 21:14 62:5
associations 18:20
assume 62:18 91:21
assumed 27:5
astonishing 41:20 51:18 63:21
Atlanta 1:15
attached 81:19,21 83:9
attack 62:12,17 65:25
attacks 65:22
attempt 34:16 37:1 37:23
attempted 35:11 63:3 93:1
attention 87:5 98:12
attributed 15:7
attributing 40:10
attribution 40:6
AUDIO 2:8
audio/visual 4:22 10:24
author 16:1 27:23 35:9 51:15 71:9 71:14 72:6 73:8 97:16
authored 71:10
authorities 72:3 77:24
authors 19:15 29:13 65:7 66:6 66:10 77:3 99:1
available 4:14 28:19 90:15
aware 6:1 7:8 13:2 42:12 45:5 60:23
a.m 1:6 11:24,24

B

B 2:5 3:12 14:25
back 20:14 36:11 40:21 42:21 45:22 47:15 48:3 60:19 67:22 68:8 69:13 74:6 75:3 86:18 99:7 100:22
backdrop 72:17 77:2
backfiring 99:20
background 31:4 62:1 77:12
backwards 91:22
bad 50:4 82:7
balances 69:7
based 19:8 38:20 49:21,22 87:16 90:24
basically 91:18
basis 20:3 30:22 33:17,25 38:18 52:16 77:9
BB 97:10
bear 46:3 84:12
bears 15:12 27:2
beginning 6:23 41:13
behalf 10:15 60:8 79:24 86:12,12
behold 76:5
believe 42:7 48:1 55:10 68:20 69:12 96:1
believed 18:23 50:13
believes 39:10 62:11
belong 44:10
bench 11:19
benefit 7:22
Berman 1:10,11 4:7,8,9,19,25 5:3 5:9,12 7:1 9:22 10:7
best 49:18 52:25
better 61:11 63:7 65:15
beyond 95:24
bias 41:20 42:6,6 43:4,6,7
bibliography 92:16
big 60:18,24 63:10 76:21 77:13,14
bigger 98:25
billion 14:24,25 15:1
binder 31:25 35:18 53:2 54:25 55:7,9 58:11,13,21,23 59:2,10 79:10,15 84:2 91:8 99:19
biopsy 83:7
bit 4:21 16:11 17:24 46:2 50:4 52:24 77:13
bizarre 86:5
blame 50:16
blank 27:14,14 36:3,8
blood 27:10 40:5 91:20
board 67:23,24 68:7
body 78:24 91:19 92:17,23
bold 52:21
book 20:1 72:14 73:8,10
bore 6:2
box 84:20
breadth 65:9
break 96:13
Brent 69:17 74:4 86:11 92:15
briefing 6:19 9:1
briefly 19:2 30:3 86:1
bring 81:15 83:15
bringing 85:8,8
Broadway 2:3
brought 68:8 83:13 98:11
Brown 69:16 72:23 74:3,17 78:19 79:6,15,17,25 80:11,24 81:3,13 81:18 82:11 86:10 93:8 98:11
Brown's 98:12,13 98:13
BUENZLE 2:8
bullet 22:8
bunch 62:20 93:20 93:21
burden 78:24 92:17 92:23
BUTLER 2:2,5

C

C 101:1,1
calculate 91:21,22
calculation 78:24 92:1
call 4:13 7:2,2 8:8 35:5 41:6,7 87:5
called 16:17 26:19 27:1,6,6,9 39:3 45:23 47:1 63:11 67:23 76:5
calls 70:5
capable 15:19
care 76:13
careful 25:14
carefully 38:22 44:2,2
case 6:3,7,9 15:23 15:24 16:4,6,9,13 16:17,18 17:11,11 18:19,19,23 24:4 24:6 26:18,18 27:3 29:4,8 30:1 30:16 32:14,15,23 33:1,3,4,5,15 34:9 34:11,11,24 35:4 35:5,12,12,17 38:13,20 39:1,1 39:21,23 40:11 41:12,16 46:15,16 46:17,19,22 47:2 47:18,21 48:3,9,9 53:23 54:1,16 56:16,21 57:20 58:2,16 60:21,25 61:1 64:25 65:12 65:21 69:11 70:20 75:5 76:25 77:10 78:1,12 80:15 82:5,15,23 83:2,4 84:19 85:17 88:7 88:15,16,16,21,21 88:22 90:12 95:25 99:6,14,24 100:1 100:2
cases 12:3,22 13:20 13:23 14:3,9 15:4 15:7,11,13,14,16 15:23 16:20 18:15 20:20 22:23 23:3 26:7 27:22 28:3,5 28:7,20 29:17,18 29:20 30:7,11,11 30:20 31:1,8,15 31:16 33:21 35:2 35:7,10,15 41:16 42:4 43:11 44:8,9 44:16,19 45:4,12 47:10,25 48:13,22

48:24 49:3,7,7,21 51:12,16,16,21 53:22,22 54:6,9 57:5,8,8 61:2 62:25 63:2,12,12 63:19,25 64:20 65:9,10 67:9,17 68:11 70:6,8,17 70:18 73:19 76:18 78:11 79:20 80:2 82:18 87:15,16,19 88:18 89:15,19,19 90:25,25 94:11,13 94:20,21 95:20 97:3,7 99:2
categorize 39:1
causal 18:20,25
causality 18:18 38:23,24
causation 12:20,25 13:3,23 14:7 23:25 51:3 87:20
cause 33:13,24 39:24 50:13 61:3 82:19 90:16
caused 13:5
causes 12:7 14:5 15:21 17:6,16,21
causing 22:1 39:2 50:23
caveats 20:14
center 64:24
certain 50:2,8
certainly 5:3 22:13 23:18 50:16 64:15
certainty 23:24
certify 101:5
challenge 77:6,9 95:23
challenged 54:11
challenging 94:21 94:22
chambers 100:22
chance 86:14
chapter 20:1 60:14 73:11
characterizations 58:1
characterize 44:19
charge 71:18
chart 24:11 72:15 75:3
checks 69:7
choose 5:21
chose 66:3
chosen 5:5
Christmas 97:9,11
CHRISTOPHER 1:17
chronic 92:25
cirrhosis 70:15
cite 13:19 14:10,13 25:24 63:23
cited 54:5
claim 6:9 14:5 79:2
claimed 15:6
claims 6:7
classification 30:22 35:6
classified 39:12
classifying 34:24
Clay 1:13 5:24
clean 45:24 46:1,6 48:14,18
clear 71:5 75:15 88:10
clearly 41:20 43:11
clerk 82:7
clinical 17:9 50:11 57:3,19
close 56:23 58:8 71:10
closer 56:5
Coast 6:17
coauthor 13:22 30:2,13 97:15
Cohen 2:2 3:4 10:15,18,19,22 11:2 12:1,2 24:17 25:21 32:5,7,18 33:19,23 34:3,7 39:21 40:20,22 41:1 45:12 52:11 54:13,20 56:16 57:17,25 58:3 60:13 63:13,14,23 64:19 68:10 73:14 73:21 75:1,19 83:12,13 85:19 90:12 94:10 96:15 96:16,20 98:8,10 99:5 100:7,10,16 100:19
coincidentally 88:15
collate 66:16
collateral 53:25
colleagues 19:14 85:2
collect 51:10
collected 15:23 16:3 19:8,11 25:17 42:3 58:14 66:1
collecting 22:23 66:21
collection 15:22 16:17 17:11 25:19 67:4,15 68:4 69:9
COLLOQUY 3:2
Colony 2:6
colors 46:9,9
column 47:1,4
coma 26:10 35:21
comatose 35:24
combination 37:20
combine 92:23
come 20:14 28:5 52:18 70:2 71:23 85:12 93:15
comes 20:2 25:10 35:4 37:18
comment 8:17 27:15
comments 81:18,19
commercially 90:15
commit 37:25 64:1
commitment 11:14
committee 15:3 20:24 21:5 23:12 38:23,24 45:15 62:7 67:7
committees 67:9
committing 63:4
common 41:13,25 76:2,2,8
commonly 43:10
community 19:3 23:1 31:14 57:21 61:16,20,25 62:14 62:15,16 63:17 72:12 78:15 79:8 99:3
company 1:23 50:16
company's 50:15
compare 69:2
complete 5:17
completed 6:25 10:3
completely 22:13 36:3,8
comprised 15:22
compute 41:18
computer 25:5
conceded 17:16 44:7
concern 93:19
concerned 74:5
concluded 33:15 46:15,17,19 100:24
conclusion 50:21 85:13 87:20
conduct 67:11 68:5 69:1
conducted 33:18 67:12
conference 1:7 4:13 7:2 11:23
confidentiality 31:21,22
confirm 16:15 29:16
confirmed 16:14,21 28:1 29:5,21 65:3 76:18,19 83:10 85:15
confirming 93:14
confirms 28:23
conform 43:11
confusing 88:18
connection 50:11 66:24 74:10
consensus 61:15,19 61:21,24 62:11
consider 50:17,18 52:2 73:16 76:15 77:3,4 98:15
considerable 7:6
considered 28:12 57:11 72:3
consist 84:6
consistent 60:6 64:9 83:7
constant 96:7
constitutional 64:5
consumed 20:10
consumers 14:25
contacted 86:8
contain 98:19
context 14:22 59:7
continue 92:4
continued 2:1
continues 92:5
continuing 6:24
contradictory 95:3
contravening 94:5
contributed 83:4
contribution 69:4
control 16:22 17:10
controlled 16:23
controversies 22:4
controversy 22:5 22:10,16 23:17,17
conversation 49:3
conveys 45:25
convinced 57:20
convincing 23:5
coordination 9:14
coordinators 24:18
copies 5:13 9:1,7 10:4 26:1
copy 7:13 26:3 55:5

62:18,19 73:24 83:22,23 84:3
core 13:3
coroner's 34:19 37:3,4,5 38:17
correct 16:18,20,22 17:1,22 30:23,24 35:7 39:2 43:2 55:13 85:2 101:6
corrected 68:9
correcting 49:4
corrections 87:3
correctly 97:1
correlate 75:20
counsel 16:2 21:1 32:1 52:7 86:10
counter 26:23
country 6:17
county 37:5
couple 28:8 49:15 49:16 64:7 93:18
course 20:4,7 27:14 30:17 34:4 38:14 53:4 54:15 67:14 84:25 95:4,6
court 1:1,23 4:2,18 4:24 5:2,7,11,15 5:23 7:15,25 8:5 8:10,14 9:2,11,12 9:21 10:5,6,11,17 10:21 11:1,12,21 12:1,12 13:1 18:18 25:20 26:5 32:2,4,6,16 33:16 33:22 34:2,6 40:21 45:10 52:9 52:12,15 53:7,9 53:13,14,15,16 54:16 55:1,6,7,11 55:14,19,22 58:21 58:24 59:4 60:23 61:18 66:5 71:3,4 71:25 74:1 77:7 79:12 81:5,16,22 83:25 84:4,16 86:2,24 87:2 88:20 89:8 91:7 91:10 93:23 96:12 96:18 98:7,9,15 99:3,5,9,11,17,25 100:9,12,15,21
courtesy 5:13 10:4
courtroom 70:3 79:7 80:12 81:3 81:11
courts 8:22 77:22
court's 87:5
CR 37:10
created 25:13
credibility 30:20,22
credit 5:7
CRF 30:23 31:19 31:24 32:2 33:8 33:25 34:17 36:2 36:8 37:10 38:21 39:16,23 41:5,8 43:15 49:12,14
CRFs 15:25 24:17 25:3 30:5,15 39:9 44:25 45:4 66:2,7 66:13
criteria 32:20 39:23 40:1,6,10 41:3,22 42:4,23 42:24 43:16,24,25
cued 73:20
current 56:5
currently 7:18
cut 37:22
cuts 5:16
cutting 37:25

D

D 3:1
daily 56:10,20 81:12
Dallas 24:21 29:10
data 12:24 13:18 16:3,3,13 18:23 19:8,11 24:24 25:3,7,9,14,16,19 28:6,18 34:23 39:22 41:14 42:3 45:23,24 46:1,6 46:13,14 48:14,18 49:6,23,25 50:2,4 50:4,8,18,19,20 51:3,10 52:2,3 53:20 55:24 57:3 57:19 64:8 66:21 67:4,15,23 68:4,7 69:9,9 76:12 77:10 82:10 87:22 96:8 97:1,6 98:3 98:19
database 25:5,9,11 29:14 54:23 56:3 56:3,4,9,10,25 57:1
databases 56:22
date 26:9 36:6 101:13
dated 9:25
Daubert 10:2 12:15 53:14 77:8,8,19 81:9,9
Davern 13:21 29:25 72:5,21 73:11 93:4
Davern's 79:11
David 2:2 10:14
day 12:7 13:14 17:6 17:21 19:5,17 20:11 36:1 46:23 46:23 48:14 53:24 56:2,5,11,23 60:5 64:10 80:11 89:1
days 36:25 41:16 42:1 43:11 46:23 49:15,16 88:23 89:2
day-to-day 6:23
deadlines 7:4
deal 60:24 76:21
deals 59:11
death 34:18 38:16 38:21
debating 72:10
decades 62:11
decide 42:13 77:7
decided 42:22 48:5 49:2
declaration 25:1 29:1 48:19,20 66:20 67:25 73:22 75:25 83:1,10 85:5,18,23,24 86:17,21 87:12 88:8 90:5 93:23 95:13
declarations 44:23 71:3,25 86:23 97:19
declined 98:13
defect 6:8
defend 35:11
defendant 10:13 54:11 57:6 62:2,3 65:4 75:24 95:7
defendants 2:2 5:4 5:21 6:14 8:11 10:16 53:15 64:22 69:15 75:10 77:14 82:14 85:17 89:7 92:10 95:23
defense 6:6
defined 13:13
defining 56:20
definite 97:17
delete 47:2,3 49:2
deleted 48:6
deliver 7:16
demonstrate 91:23 93:6,19 100:4
demonstrates 100:6
demonstrative 4:22
depends 36:16
depose 49:17
deposed 49:18
deposition 6:6,10 7:19,19,20 13:23 16:15 17:4 19:19 20:25 22:7 28:25 29:6 30:4,9 35:3 51:18 58:19 59:3 59:9 68:21 75:14 79:11 87:4 92:14 98:13,21
depositions 5:17 6:16 9:6 10:2 11:4 49:13 97:21
describe 14:14 16:13 82:23 87:20 92:2
described 16:8 27:21 48:23 63:11 65:1 67:24 82:25 83:7 88:8 95:2
describes 27:22 45:25 73:23
describing 87:7,19
description 3:13 89:5
descriptive 87:22
design 6:8 12:18 16:15 18:5,17 50:24,25
designations 6:6
designed 16:23 17:2,4,14,19 24:7 24:8 29:16 51:2 62:20,21 87:1
designing 50:22
detail 33:2
details 34:10
determine 92:24
determining 56:18
develop 57:12 60:4
developed 59:21 76:3
diagnosis 84:14,18
died 34:17,21
differed 28:14
difference 77:17 87:17 89:16
different 5:6,6 7:23 24:9,19 27:16 33:8 50:12 56:22 88:18
differently 17:24
difficult 64:12 82:13 94:9,10 95:9
difficulty 56:20

64:16 88:2
digits 31:18
dime 71:12,16,20
directed 34:25
directions 7:24
directly 69:6
disagree 22:18,20
disagreements 22:18
disclose 42:5 65:7
disclosed 31:8,21
discovered 15:7 31:7
discuss 15:13,13 30:6 45:8 52:7 69:18 76:20 85:25 94:10 98:21
discussed 22:11 41:5 67:10,16,18
discussing 59:12,18 60:21
discussion 4:4 7:6 35:15 63:24
disease 21:15 62:6 69:5 70:15 72:5 73:5,9,11 83:8 89:12
display 4:22
displayed 5:10
dispute 38:18 51:9 95:11
DISTRICT 1:1,2,8
divided 17:6,21
diving 57:24
doctor 34:20 37:7 38:7 44:14 57:12 76:24 81:12 84:17
doctors 36:21 63:8 71:22 94:24
document 41:23 43:16,17 50:1 54:19 55:1
documentation 41:9
documented 41:8 42:21,25 43:2,10
documents 8:21 12:11
doing 8:24 47:20 52:22 62:9,10 68:15
dose 13:10,11,13 15:8 18:13 21:7 23:13 27:4 32:14 32:15,17,19,24 36:7,9 38:3 39:4,8 46:23 47:17 49:8 54:15 55:17 56:6 56:6,10,21 57:10 61:5,5,10 65:3,16 70:20 75:18,20 76:19 80:21 82:20 83:10 85:12,15 87:8 90:1,17 91:12 92:24 93:7 93:14 96:24,24,25 97:7 98:4 99:22 100:5,7
doses 13:4 14:12,24 17:6,16,21 19:16 28:19 29:16 30:6 37:19 50:24 56:5 56:23 76:4
dosing 26:7 30:21 30:23 36:17 46:22 46:24 51:11 63:18 64:11,17,21,22 88:3,6 91:23 92:25 94:20,22 95:8,15
Dr 13:18,21 16:1 16:14,21 17:3,16 17:19,22,23 18:6 19:13,14,18 20:5 20:12,16,22 21:4 21:8,10,13 23:5,8 23:11,15,18 24:25 25:13,21,23 27:23 27:24 28:1,4,16 28:25 29:12,25,25 30:8,8,19 31:14 32:14 33:3,14 34:23 35:3,9,11 35:12 37:2,9 39:6 39:10,10,22 40:9 40:17 42:19 43:3 43:9,12,14,15,17 43:18,19 44:7,17 44:18,24 45:4,14 46:1,5,13 47:5,8 47:14 48:5,18,19 48:23 49:13,14,14 49:25 50:10,14,25 51:17,19 52:1 58:6,10,18 59:11 60:14 64:24 65:3 66:12,13,14,19 67:8,25 68:20 69:2,16,17,17 71:17 72:2,5,21 72:21,21,22,23,23 73:8,11 74:4,4,17 74:17 75:6,6,14 75:25,25 76:16,17 76:19 78:6,19,20 79:6,11,15,17,24 79:25 80:11,24 81:3,13,18 82:11 82:15,17,24,25 83:3,3,9,10,23 84:23 85:2,4,7,9 85:14,18,23 86:9 86:9,12,13 87:4 88:8,15 91:9 92:10,10,13,15,20 93:3,3,4,8,9 94:6 94:12,13,14,18 95:11,12,12 97:3 97:4,15,16 98:11 98:12,13,13,18
draft 66:17
drafted 73:17 86:22,22
drafts 30:14 86:18
drinking 34:13 35:25
drive 7:15 8:3
Drs 18:22 22:24 74:3 86:10
drug 19:17,22 21:6 50:12 58:7 65:18 69:21
drugs 69:25
drug-induced 72:5 72:20 73:5,11 83:7
due 6:11,12,20 31:21 70:12,19 81:1 85:11
duration 36:8
d-CON 34:15,15 35:4,5,12 36:24 46:16 47:3
D.C 1:18

E

E 3:1,12 101:1
eager 41:16 42:4
earlier 27:21 29:7 50:7 82:3
early 41:16 42:1 43:11 61:9 65:23
East 1:15 6:17
EASTERN 1:2
Edition 25:25
editors 31:10
effect 68:6
effective 20:10
efficient 11:8
eh 50:4
EHRs 56:2,9
either 20:3 40:2 49:20 61:4
elected 21:21,21
electronic 1:21 101:7
elevated 57:4
email 45:24 80:11 81:17,25
emails 79:11 80:5 98:12,14
emphasize 65:11 71:21 78:6
emphasized 25:13
employ 79:20 81:10 93:10
employed 69:8
encephalopathy 26:10,13
encourages 86:6
ends 88:16,17
enroll 24:8 79:19
enrolled 26:12 36:22 84:9
enrollee 42:15
entered 25:4,7
entitled 5:19
entry 25:8
epidemiological 17:10 51:5
epidemiology 57:19
equal 72:13 89:20
equipment 10:18
errata 49:5
error 39:13,14 44:12,15 51:19,20
ESQUIRE 1:10,13 1:17 2:2,5
ESR 100:23
essentially 11:7 15:5 16:19
establish 12:19 13:23 18:20 54:10 97:2,6 98:4
established 18:24
establishes 98:5
establishing 15:20
estimated 92:17,23
ETOH 26:16
evaluate 39:7
evaluated 15:14 30:5
evaluation 48:21
event 4:3
eventually 47:19
everybody 22:2 93:4 94:6
evidence 6:12 11:9 12:11,13,15,25 13:2 14:8 22:14 31:8 32:23 52:18 56:17 57:15,18 65:13 73:17 96:9 98:15

exactly 17:23 49:25 86:7,20 89:1,21
examine 49:12,13
examining 51:8
example 8:25 35:14 51:25 54:18,24 82:12 92:13
examples 51:13 79:9
exclude 34:1
excluded 46:10,16 46:18,20 47:7,9 47:13 48:21,25 49:6,21 99:1
excreted 92:6
excuse 14:20 29:25 60:25
exhibit 28:24,24 82:14 83:9 84:1
exhibits 5:13 53:4
exist 76:22
existing 22:14
exists 77:20
expect 42:24 95:9
expected 74:17 94:23,24
expects 43:3,5,12
expedited 7:11 8:2 52:16
experience 60:6
expert 12:6 14:7 30:1 74:3,15 77:5 80:4,12 95:24
experts 13:7,19,21 14:10,14 44:24 64:23 69:16,19 72:18 73:3,5,12 73:16 75:5,6,10 75:23 76:11,12 79:3 81:10 89:25 90:20 91:6,16 92:9,10 94:7 95:23 97:3,5 98:25
expert's 97:21
explain 37:17 46:3 76:3,9,9 98:14
explained 23:19 40:9
explanation 49:5
explore 79:3
exposed 90:9
extensively 66:20
extent 9:8,11
extra 5:7
eye 97:12

F

F 1:7 56:9 67:5 101:1
fact 28:25 29:21 38:15 44:21 45:21 54:6 57:17 58:11 61:22 68:20 70:23 73:7 74:13 76:11 76:15 87:14
factors 26:15
failed 26:21 73:16 76:15,20
failure 6:7,15,19 7:7 12:4,8 13:5 14:6,11,16 18:8 33:13 51:8 54:7 56:4 57:13 59:21 59:24 60:4,7,9,22 61:4 62:7,13,22 63:2 65:2 66:22 67:2,11 68:8,13 69:20,23,24 70:8 70:10,12,18 71:8 71:11,16,18 72:20 73:1,6 74:10,18 76:4,25 77:3,15 78:21 79:18,19,20 79:25 80:2,8,9,13 80:15,17,20,25 81:1,5 82:4 83:6 85:10 87:21 88:13 89:6,11,20 90:3 90:16,18 91:1,2 92:3 93:10 98:3
failures 70:17
fairly 65:8
falls 30:20 48:9
familiar 55:1
farce 79:13
fashion 41:22 74:16
fast 6:13 7:24
father 36:20 37:24
faulty 50:17
favor 22:14
faxed 24:21
FDA 14:1 15:3 20:23 21:3,4,11 31:9 44:21,25 45:5,14,17 49:11 51:21 53:20 54:18 54:22,25 55:3 56:3,15,19,19,24 60:10 62:4,4,6 65:13,14 77:25 78:4,7,18 93:13 93:16
features 76:3
federal 12:14 50:6 78:4
federally 59:20
feel 5:18
fell 28:20
female 34:13 36:24
Ferry 1:15
fewer 70:18
field 39:14 73:5
fields 73:3
figure 8:8
filed 10:2 79:16 80:12 85:17,23,24 86:8,12 87:1
filing 60:21
filings 10:4
fill 84:20
filled 24:17 25:4 84:8
final 31:1 84:14,18
finally 13:24 26:25 27:8 38:19 50:10 98:17,23
find 40:11 78:1 84:13 85:20 94:25
Finlay 22:16
first 4:10 12:9,18 15:18 18:19 25:24 31:14,17,18 35:9 37:9 41:10 52:14 54:6 57:14 62:23 66:17 70:25 74:14 77:18 80:22 85:17
FISHBEIN 1:11
fits 65:20 87:22 89:1 95:19
five 49:6 68:19 88:23 89:2
five-year 80:1
Flamm 64:24 65:3 69:17 72:23 73:8 74:4,17 76:16,19 78:20 82:17,24 83:10 85:2,7,9,14 86:10 88:15 92:13 92:20 93:9
Flamm's 82:15 83:3,3,23 84:23
flawed 31:1 35:16 44:9,17 49:24 50:2,18,19 51:12 51:24 52:2 79:3
flaws 12:23 39:6 68:23
focus 21:22 27:17 66:4 70:1 83:18 83:20
focused 55:2 66:3 69:19 89:14
follow 5:15 42:18
followed 28:17
following 21:3 58:18 71:3
follows 12:17
follow-up 15:11
footnote 56:8
foregoing 101:6
forget 70:4
form 24:4 26:19 27:3,14,16 30:18 35:17 37:5,8 83:14,18,20 84:7 84:8,15 85:21
format 5:6
forms 15:23,25 16:4,9,11 24:6,22 25:4 29:4,8 38:13 68:25 78:13 82:5 84:6,7
formula 91:18,18 93:5,17
forth 60:1 86:18
forthcoming 15:16
forum 60:10
forward 40:24,25 40:25 58:9 71:23 93:15
found 40:16 41:19 45:21 93:16
Foundation 62:6
four 26:11,11 33:9 33:11 37:7 38:15 44:8,16,18,18 70:3,4
fourth 55:10
frame 11:4
frankly 41:19 59:6 59:7 63:20
freely 95:13
Friday 85:17,24 87:1 94:13
friendly 22:18
frivolous 87:1
front 18:1
fulfill 39:23
full 6:2
fund 71:17
funded 59:20 78:5
furnished 9:9
further 70:21 82:21

G

GA 1:15
garbage 25:15,15
gatekeeping 12:14
general 19:21,22
generally 9:20
generic 36:5 60:24 61:13
genetic 75:24 76:1

76:2,8 98:19
GEREL 1:17
getting 25:14 64:16
give 4:12,15 8:23 21:18 26:2 62:19 79:8 82:12 83:23 84:11 87:19 94:25
given 5:1 9:19 34:23 36:20 41:11 75:11 88:24 91:23
gives 92:6
giving 61:11 64:16 81:24 88:2,3,13
global 59:19
go 17:24 33:1 34:10 40:21 42:21 47:15 48:3 53:25 56:14 56:14 58:11,13 59:10 60:10,18 63:22 69:13 72:8 72:16,24 74:6 75:3 85:4 89:23 94:12,14 99:23
God 97:21
goes 25:15 57:12 64:6 77:10
going 5:10 6:2,13 7:23 8:18 10:12 10:15 15:24 20:14 24:4 27:5 30:2 31:23 32:7 34:9 34:10 40:14 45:10 45:15 46:12 47:11 48:10 52:25 53:21 58:12 74:25 75:18 77:13 79:6,8 80:18 82:12 95:9 95:21 96:13,23 97:10,11
good 5:22,23 8:14 8:15 25:14,16 41:15
gotten 88:25
government 78:4
grades 26:11
Grail 93:17
grams 12:6 13:14 14:5 17:6,21 18:9 19:5,16 20:11 23:6,10 28:9,21 32:20,20,21 35:25 36:1,11 40:3 48:14 56:1,5,11 56:23 57:3,23 58:8,10,18,23 59:24,25,25 60:5 61:4 64:10 76:6 76:25 83:11 87:8 88:23 89:1,6,20 98:19
grant 43:5 67:1 71:9,19
graphics 100:13
gray 46:10,10,17 46:18
graying 47:6
great 33:2
green 46:19 47:18
grotesque 45:7
group 6:16,20 7:7 12:4 14:1 15:5 16:22 17:10 47:25 54:19,25 55:4,12 56:4,15,19 57:8 59:21 60:9,22 62:4,8,13 65:14 66:23 67:2,11 68:8,13 69:23,24 71:8,18 74:19 76:7 77:15 78:21 79:18,19,25 80:2 80:9,13,20 81:5 87:22 88:7,13 90:19 93:10 98:3
groups 80:8
Group's 82:4
guess 21:8
guilty 10:19,22
guise 94:2
gun 90:15 97:11,13 97:21,22 99:20
guys 81:6

H

H 3:12
half 60:20 63:3,6 91:14,21 92:23 96:5
hand 32:2 53:8
handful 32:12,13 89:14
handle 96:25
handling 96:23
hands 7:20
handy 40:8
hand-up 5:14
Hang 39:17 74:1
happen 68:24
happened 29:3 65:24 69:11 80:3
happens 22:2 90:11
hard 26:3
harm 63:4
Hayes 61:1
hazardous 64:10
head-down 25:7
Health 53:19 66:25 67:6 68:17 69:10 78:9
hear 52:15 53:19 75:1,19 77:10
heard 21:16 31:13 72:17 73:13 89:19 97:22
hearing 7:3,8,11,16 77:8
hearsay 98:16
heavily 61:14
heavy 36:25
help 29:16 76:9 85:21
helped 33:20
helpful 9:16
HENRY 1:14
hepatic 26:10,13 56:2
hepatitic 35:21
hepatitis 70:14 73:3
hepatologist 13:17
Hepatology 31:11 51:22 53:18 78:19
hepatotoxicity 20:6 57:4
herbs 26:22
hey 49:5
high 75:20,20 92:6 92:7 97:6
higher 77:21,22 78:3
highest 77:24
highlight 26:20
highlighted 28:10
highlights 39:6
highly 51:12
histories 26:7 30:21 63:15 95:1
history 30:23 36:20 37:24 63:18 64:17 64:21,22 88:3,3 91:23 94:20,22 95:2,8,15
hoc 90:25
holder 71:9
Holy 93:16
honor 4:8 5:18,22 6:1,20 7:8 8:13,23 9:8,18,23 10:14 10:20 11:3 12:2 13:12,24 20:22 21:18 25:24 30:1 31:5 32:22 33:2 36:3 39:5 41:19 42:5 45:7 48:17 50:21 52:5 53:2 55:21 63:20 66:9 66:19 69:7 73:20 73:25 80:23 83:24 84:13 90:23 93:23 93:24 94:8 96:3 96:20 97:8 98:23 99:14 100:8,10
HONORABLE 1:7
Honor's 5:12 9:15
hooey 93:21
hope 12:12
hospital 27:12 40:5 57:9 76:23 88:25 89:2 100:2
hospitalization 41:15 88:22
hour 11:15
housekeeping 100:10
human 60:3
hundred 80:7
hurry 47:11 48:10
Hy 21:18
hypothesis 50:22
hypothetical 92:1

I

idea 5:10
identical 54:22
identified 15:14 16:4 28:5 68:6
identify 12:22 23:3
identifying 88:14
idiopathic 84:22
ignored 34:3
ignores 60:15
illustrate 58:2,4 62:13 73:7 99:23
illustrates 79:13
immediately 35:11
importance 73:23
important 14:15 18:17 25:6 26:17 29:2 43:1 48:12 48:16 49:24 52:16 52:19 57:16 61:13 63:5,10 66:18 72:10 73:17 74:24 77:20 83:14,17 86:4 90:22 92:8 95:19
importantly 54:13 69:17 78:19 80:6
inappropriately 92:7
inattention 79:19
include 95:12
included 43:21 44:5 80:6 82:18 90:13

including 26:22 57:6 61:10 64:21 67:3,4,4 73:18
incorrect 38:2 91:24
increase 55:17 61:12
independent 77:23
indeterminate 84:22
indicate 47:6,16 90:1 97:17
indicated 52:23 54:13,20 56:24 57:6 58:5,6,10 78:7 88:22 90:1,3 92:13
indicates 56:9 57:3 84:18,19 88:1 90:6 91:3
indicating 34:20
indicia 77:20 91:3
indiscernible 5:8 7:19 8:4,4 9:16 24:15 40:18,19,24 47:3 84:15 97:14 100:17,20
individual 42:22 57:5 68:11
individually 42:17 94:15
individuals 56:7
induced 59:23
indulgence 99:15
inevitably 68:24
information 4:16 8:21 9:10 15:15 15:17 27:7 30:16 30:18 31:20 37:11 37:14 39:8 48:12 64:11 66:14 68:3 86:16,16 88:14 95:4
informed 41:24
ingestion 14:12 15:8,20 17:6,21 18:2,9,13,25 19:4 20:20 29:23 36:24 39:12 48:13 56:1 93:20 98:20
ingestions 22:4,8
ingredient 15:1
initial 80:24
initially 38:10
injury 13:5 22:2 33:13 50:14 56:2 64:8 72:20
Institute 53:19
Institutes 66:25 67:6 68:16 69:10 78:8
institution 34:19 36:16 65:1 88:17
instructions 61:11 65:15
intend 59:6
intended 59:6
intent 5:4
interesting 83:13 83:19
interestingly 73:9 75:22
internal 67:24
investigate 86:7
investigator 36:21 36:22 41:7 51:14 71:7,7,13 72:6 79:23
investigators 24:19 30:8 32:13 33:7 67:14 68:1 90:19
invite 97:25
invited 20:23 21:17 21:18
involved 11:4 54:16 66:12 68:14 82:2
involves 6:7 34:12 91:15
involving 50:12 92:12
IN-PERSON 1:7
issue 6:20 7:20 42:11 53:25 58:17 60:25 65:22 75:8 75:8 79:22 85:17 85:19 87:14 89:24 91:14 93:13 96:6 99:19,20
issues 6:2,24 52:6 53:25 54:5 58:16 63:17 67:10,15 72:10 80:21,22 85:16

J

Jackson 6:8 13:15
January 9:25 29:1 69:14 70:3 82:8 82:17 86:22 89:8 90:23
Jersey 4:6,11,16 6:20,22 8:19,24 13:16
jive 78:14
job 66:14
Johnson 4:14 7:3 7:17 8:25 9:3,14 9:18 10:23 52:20 61:18,23
Johnson's 8:6 9:24
Jones 2:5 8:12,13 8:15,15 10:14 11:19 100:21
Journal 31:10 41:25 53:18 78:19
Judge 1:8 4:13 7:2 7:3,16 8:6,25 9:3 9:14,18,23 10:23 11:18 52:14,20 61:18,23
Judi 2:9 101:4,13
jump 53:1
jumping 40:22
June 45:14,18
jury 6:11,25 77:11 89:18,18 96:9

K

K 1:18
Kaplowitz 13:18 72:2,21 93:3
keep 9:18 29:2
keeps 40:22
Kemp 10:1,24
key 26:4
kind 90:4
kinds 68:25
knew 20:20 37:14 38:14
know 5:16,19 7:10 19:21 23:5,8,11 23:15 34:4 36:6,7 36:7 38:8,10,11 43:17,18 45:1 51:21,22,23,23 63:17 74:7,8,9 78:10,11 80:13,14 80:15,16 81:6,25 82:1 83:16 84:25 85:3,3,14 87:17 93:16 96:22 98:6 100:1
knowledge 61:7 75:12
known 5:4 16:8 17:11 21:15,19 33:12
knows 54:17
Kort 76:6

L

labs 41:18
lack 23:23,24 43:4 43:6,7
largely 90:19
larger 57:18,18
largest 60:6
Larson 12:5,19,22 13:8,19 14:2 15:4 15:10 16:1,14,21 17:3,14,19,19,23 18:22,24 19:7 20:5,7,8,12,16 22:25 23:4,8 24:3 24:20 27:17,23 28:1,4,16 30:8 33:18 35:9,11 37:2,9 39:6,10 43:14,17,19 44:7 44:18 45:16,18,19 45:22 46:5,7,14 47:5,8,14,24 48:6 48:18,23 49:4,14 50:25 51:1,19 52:1 54:21 59:13 59:18 62:17 66:2 66:14 71:10,13,14 72:6,22 75:6 87:8 92:10 94:13,14 95:12 96:10 97:4 97:15
Lastly 9:13
late 6:4
LAURA 2:8
Laurence 1:10 4:8
law 1:10 82:7 86:6
LAWRENCE 1:7
lawyers 86:6,9,18 86:23
lead 7:18 16:1 51:14,14 71:14
learn 75:5 85:12
learned 25:8 48:24 49:19 83:8 97:20
Lee 17:16,22 18:6 18:22 19:13,18 20:22 21:4,8,10 21:13 22:24 23:5 23:11,15,18 24:25 25:13,21,23 27:24 28:25 29:12 30:8 30:19 31:14 32:14 33:3,15 34:23 35:3,12 39:10,22 40:7,9,17 43:15 43:18 44:17,24 45:4,14 46:1 48:5 48:19 49:14 50:10 50:14,25 58:6,10 58:18 59:11 60:14 66:12 67:25 69:2 71:6 72:21 73:22 75:6,14 76:17 79:24 85:18,23,24 86:9,9,13 87:4

90:5 91:9 92:10 93:3 94:6,18 95:12 97:3,16 98:18
Lee's 43:9 46:13 51:17 75:25 82:25 83:9 85:4 88:8
left 87:10
let's 17:13,24 19:2 35:17 39:16 40:11 42:21 48:2 52:9 85:16 91:7,14 94:15
level 27:10,10 36:13,14,16,18 40:4 92:6,7 100:4
levels 74:20,25 75:1 97:23
LEVIN 1:10
LIABILITY 1:5
life 81:12 91:14,21 92:23
limb 95:24
limine 9:15
limit 28:13
limited 4:2
line 30:9,10 59:12 60:3 72:18
lines 30:12 65:13 98:21
lining 6:10
list 6:12 36:2
listed 36:4 70:22 82:20
literature 57:7 59:22 60:15 78:14 87:24 95:14
litigation 1:6 9:20 14:4 31:7 69:19 77:23 85:9 90:21
little 16:11 17:24 46:2 50:4 52:24 64:10 65:6 77:13 84:20
liver 6:15,19 7:7 12:4,7 13:5,5 14:6 14:11,15 18:8 21:15 22:1 33:13 33:13 50:13 51:8 54:7 56:4 57:13 59:21,23 60:4,7,9 60:22 61:4 62:6,6 62:7,13,22 63:1 64:8 65:2 66:22 67:2,11 68:8,13 69:20,23,24 70:8 70:10,12,15,17,18 71:8,11,16,18 72:5,20,20,25 73:4,5,6,9,11 74:10,18 76:4,24 77:3,15 78:20 79:17,24 80:2,8,8 80:13,15,17,20,25 81:1,4 82:4 83:6,8 85:10 87:21 88:13 89:5,11,11,20 90:3,16,18 91:1,2 92:3,5 93:10 98:2
LLP 1:14,17 2:2,5
lo 76:5
location 38:9
long 54:16 65:24 90:9
look 8:3 16:10 19:2 24:4 28:13 34:9 35:17,18 39:16 55:15 56:8 62:20 62:21 66:7,9 69:1 74:7 80:14 87:2 91:20 97:25
looked 28:6,17,18 29:3 41:15 54:19
looking 28:22 45:22 46:13 52:21 66:12 74:15
looks 21:11 81:17
loop 9:19
Lortab 36:5
Los 37:6
lot 7:23 15:24 21:16 44:20 49:17 63:14 65:4 68:10 69:25 76:13 95:7 98:11
low 13:10,11,13 14:12 17:16 18:13 27:4 29:16 30:21 32:14,17 47:17 49:8 50:24 54:15 65:3 70:20 76:4 97:5,7
lowered 55:17 65:16
lowering 61:10
low-dose 12:3,22 12:24 13:20 14:3 15:4,20 18:2,15 18:25 20:20 22:4 22:8,23 29:20,22 30:5,7,16 31:16 33:4 39:1,12 44:9 44:19 48:13,24 49:7 51:9,16 54:7 63:12 67:17 73:19 76:18 78:11 82:23 87:19,21 93:19 97:2
L.A 34:19 38:17

M

M 2:2
Macrobid 33:8,11 90:11
main 4:3 29:9,19 38:8
major 95:10
making 12:12 37:23
manner 5:6,20
Manual 16:8 18:3 25:12,22,23 29:19 29:22
Manuals 67:3
manufacturer 55:24
manuscript 30:14
march 80:10 81:17 82:9,9 93:22
marching 70:2 81:5 89:8 90:23
margin 54:8,10 55:18 57:22 61:8 61:12 64:9 65:17 93:20
mark 22:5,9
marked 3:13,14 28:24
Market 1:24
MARKETING 1:4
math 37:21
Matt 40:7
matter 52:17 68:12 100:11 101:8
maximum 19:16 32:19 36:18 56:6
McNeil 15:16 56:16 57:21 61:6,20,25 62:11 66:1 74:19 85:23 86:12,20 90:20 93:15
McNeil's 65:22 73:16 76:11 80:4 89:25 91:6,17
MDL 9:2 13:3,22 30:2
mean 47:20 75:9 82:6 87:7 95:3,5 95:15 96:8
means 22:17 25:8 26:13 40:1 46:10
meant 26:20 47:15
measure 91:19 99:22 100:7
measures 61:9 99:21 100:6
median 56:10,11 87:7,7
medical 13:3 22:25 34:19 46:12 57:7 57:21 59:22 60:14 61:16,19,24 62:14 63:15,16 64:24 72:11 78:14,15 79:7 84:17 88:3 95:14
medication 33:10 36:2 64:4
medications 26:19 26:21 32:10
medicine 18:21 22:17 39:15 44:13 44:15
meds 26:23
meet 7:4 43:25 86:14
meeting 21:16 23:16 67:13
meetings 67:8
meets 81:13
member 38:24
members 69:23 74:18
memo 82:7,8
mental 26:13 35:22
mention 29:23 30:3 48:18,19,20
mentioned 7:1 9:17 24:3 27:18 70:13 70:14
met 86:14
methodologically 35:15
methodology 12:21 12:24 23:2 24:2 31:2 39:7 41:21 44:9,22 66:6,19 68:12 69:8 70:5 78:10 81:11 82:5 98:24
methods 49:22,22 51:9
meticulously 68:22
midpoint 56:12
MID-ATLANTIC 1:23
mid-February 86:15
mid-2000s 61:9 79:18
milligrams 36:11 37:14,16 38:1
milliliter 97:24
Milling 1:13,14 4:12 5:22,23,24

5:24 8:1,6,17 9:13 52:20
mind 29:2 32:1
minimum 49:20
minute 60:19
minutes 34:11 52:6 96:17,19
misfired 97:13,22 97:23
missing 24:24 68:25
moment 11:20 22:12 24:4 26:2 27:18 69:18 72:16 79:1 84:2,12 100:22
monitoring 67:23 68:7
monthly 20:3 67:7
months 26:22 41:10 71:2 78:17 80:11 82:3
morning 5:22,23 8:14,15
mother 97:10
motion 6:15 10:24 82:14 85:23 86:8 86:11,25 96:2
motions 7:21 9:15 10:1 60:21
mountain 11:8
movie 96:22 97:9
moving 18:15
multiple 6:2 58:9
multiply 37:19
mushrooms 26:22

N

N 3:1 101:1
name 80:18 81:4
nanomoles 97:17 97:24
narrow 54:8 57:22 61:7 64:9
National 1:23 53:19 66:25 67:6 68:16 69:10 78:8
nation's 72:3
NE 1:15
near 57:23 61:4
necessary 77:19
need 26:2 45:8 72:9 72:18
needs 73:25
never 27:3,4 29:3,5 30:5,5 31:8,13 38:7 41:24 43:10 44:25 45:3,4,6 49:9,10,11 76:11 79:3 92:11 93:1,9 93:22,25 95:11
Nevertheless 79:21
new 2:3 4:6,11,16 6:20,22 8:19,24 13:16 74:7 80:1 82:8
NH 71:18
NIH 31:9 42:10 43:3,4,12 44:21 45:1,6 49:11 50:1 50:1,3,5,6 51:22 67:20,25 71:9,17 77:25 78:18
NIH-funded 62:23
nitrofurantoin 33:10
non-litigation 90:20
non-party 42:9 49:16
normal 100:5
note 34:18 37:4 60:16 71:21 92:8
noted 28:6 34:16 61:19
notice 5:1,19 71:24 84:5
noting 27:3
number 3:13 21:23 31:19,24 36:14 55:3,3 58:23 61:3 61:6 70:7,11,16 82:14 85:22 87:14 88:7,16,16 89:4 89:23 92:1 99:24
numbers 31:24 93:18
numerous 61:23
NW 1:18
NY 2:3

O

O 101:1
objection 5:20 10:25 18:4
objections 31:6
observation 89:21
observations 14:18 18:16 57:19
obviously 32:13 44:17 51:12 52:16
occur 56:22 59:24 59:25,25
occurred 97:7
October 13:16
odds 16:25
offer 18:16
offered 98:12
office 10:15 34:19 37:4,5 38:17
officer 42:10
OFFICES 1:10
official 71:17
oh 37:3 40:20 41:5 75:19 97:21,21 98:4
okay 4:18 7:25 8:5 9:12 10:6,11,21 11:1 37:12 45:3 45:20 50:4,8 55:23 81:22 85:22 86:2 91:8 99:8,17 100:15
old 96:22
Olsen 2:9 101:4,13
Once 25:2
once-a-year 67:13
ones 79:12
onset 26:9 64:7
on-goings 4:17
Oops 98:5
Operation 67:3
Operations 16:9 18:3 25:12,22,23 29:19,22
OPERATOR 2:8 100:23
opine 21:6
opinion 12:6,6 14:7 59:22 87:12
opinions 60:8 72:12
opportunities 60:11
opposition 85:25
oral 7:22
order 5:12 7:5 9:24 9:24,25 26:12
OTC 26:23
ought 60:16 70:24 95:25
outcome 84:8
outside 28:20 61:21 81:3
outstanding 35:14
overdose 21:25,25 27:2,5,6,19 32:11 34:14,21 36:10,24 37:6 38:5,8,15 46:22 47:17,22 64:3 97:18 98:5
overdoses 22:1 27:20
over-the-counter 15:2

P

PA 1:4,12,24
Paces 1:15
packed 4:3
page 3:1 24:7 25:25 27:21 30:9,12 55:3,14,15,16 56:14 58:19,22 59:11 63:23,24 73:23 83:1,1 90:6 91:9 92:14,21 98:20
pages 73:25
paid 71:12,16,19
pain 63:8 64:4
paper 12:5,19 13:8 13:13,20,22 14:2 16:2,4 17:14,14 18:6 19:7,15 20:19 24:20 27:19 27:24 28:1 29:4,8 30:2 31:3 33:18 35:10,10,14 38:12 43:22 44:5,5,11 45:20 51:15 59:13 59:19 63:24 65:6 66:9,9,11 72:7 80:18 87:22 95:18 95:19 99:1
papers 44:23 61:22 79:16 98:18,22,22
paperwork 79:20
paper's 96:10
paragraph 13:7,9 15:10,12 23:4 27:20 31:3 32:21 54:21 55:2,3 87:6 87:9
parcel 13:2
Park 2:6
part 12:14 13:2 24:10 30:15 37:3 41:8 42:17 45:23 47:25 57:17 61:25 63:5,9 66:11 68:1 78:20 83:15,20
participant 70:22
participate 4:15 79:25
participated 70:23
particular 55:2 62:17
parties 6:2,22 52:17 96:8
parts 27:16 65:6 83:14,17
party 10:19
passed 53:17 68:19
passeded 53:17

patient 24:11 35:21 36:3,23 43:19,20 43:21 44:3,4,4 64:25 68:4 75:18 76:5,22 82:15,16 82:19 84:8,10,14 84:19,20 85:5,6 88:13,23,24 90:9 90:11 91:21,24 92:3,24 100:3,3,5
patients 24:8 27:11 27:19 28:14 43:24 59:23 63:6 64:3 64:12,14,16 65:8 67:21,22 68:2 71:22 74:9,9,12 74:20,22 76:1,3,6 76:7 80:25 88:2,6 89:6,9,10 90:2,6,8 90:17 94:24,25 95:2
patient's 39:24
Patricia 42:8
pattern 89:1
Pause 10:9 39:19
peer 31:10 41:24 51:24 53:17 65:25 68:17 77:19
peer-reviewed 78:5 87:24
PENNSYLVANIA 1:2
people 21:7 22:17 37:8 51:23 56:23 57:9 63:3,25 71:4 72:10 76:10,10
percent 32:18 39:13 44:13,15 49:21 51:19,20
performed 42:20 73:14,19
period 6:22 11:10 11:10 19:10 36:1
permission 53:5
permitted 52:7
person 34:20 41:21 57:12 73:10 91:20
personally 65:3
person's 91:19
perspective 8:12
ph 6:3,7 22:16 53:9 60:25 61:1 69:17 74:4 76:6 86:11 92:15
phenomenon 87:21 92:2
Philadelphia 1:4,12 1:24
Phone 24:13
phrased 30:24
physician 24:22,23
physicians 22:20
picking 65:6
picture 60:18,24 63:11 77:14,14
pieces 59:8
pills 37:22,25
pinned 21:9 23:14
place 71:1
places 33:9,11 38:16
plaintiff 5:25 13:19 14:7
plaintiffs 1:10 4:9 4:21 7:10 9:4 13:1,5,6,17,25 14:10 16:2 21:1 30:1 31:6,25 42:8 44:20 52:8 61:14 75:5 92:9 96:25 98:24
plan 7:19 45:19
played 79:7
please 39:17
plug 93:18
point 4:19 16:11 21:4,5 22:8 48:17 50:1,3,5,9 54:24 56:15 57:2 58:2,3 73:7 74:18 75:23 77:18 78:16 81:15 86:20 87:18 90:22 93:8,12 96:3 99:13,23
pointed 52:20 76:17
pointing 19:7
points 4:10
poison 34:16
poisoning 47:3
polymorphism 76:8 98:18
polymorphisms 75:24
poor 25:19
portion 85:20
portions 33:6
pose 12:16
posing 12:9
positive 85:14
possibly 85:10 96:6
post 90:24
post-study 91:5
potentially 39:3
PowerPoint 5:8 52:24
practical 52:17
practice 41:13 42:1 44:15
practices 1:5 67:3
precise 32:14 64:11
predetermined 42:3
preface 19:6 21:21 59:14
prefix 88:11
preliminarily 16:12
preliminary 14:17
prepare 32:25 33:1 53:2
prepared 5:14 32:1
presence 73:18 75:15 85:6 91:11
present 32:23 38:20 94:2
presentation 4:23 5:20 11:7 21:14 21:18,19,20,22,24 21:24 52:25
presentations 5:5
presented 10:23 34:22 53:20 67:10
presently 18:18
presents 52:8 56:2 56:6 91:20
prespecified 40:10
presumably 46:7
presume 77:22
pretrials 6:24
pretty 8:6 32:16 53:13
previous 41:15
previously 9:23 76:21
primary 27:23 75:7 97:16
principal 13:17 51:14 71:7
principle 18:21 52:3
printed 100:14
prior 23:19 36:25 77:23 78:8,9
private 71:6
probably 49:10 81:1
problem 21:25 40:15 46:22 65:7 65:18 66:5 82:3 91:25 98:23,25
problems 50:8 68:3
procedurally 66:1
procedures 66:21 68:17,18
proceeded 35:22
proceeding 23:20 31:5 79:14 82:2 100:24
proceedings 1:21 101:7
process 48:21 66:16 79:2,4
produced 1:22 11:9 51:18 69:15 79:11
product 36:4 61:11
products 1:5 15:2
Professional 101:5
program 42:10
project 25:18 45:24 46:1 48:18
proof 23:23
proofs 96:9
proper 79:20
properly 43:20,21
proposition 54:4 63:21
protocol 16:8 17:25 29:15,17,19,23,24 42:17,18 50:3,5
prove 13:6 22:13 23:21
proven 93:1,1
provide 5:13 41:9 71:24 94:17
provided 9:4,15,23 10:1,3 27:15 44:25 64:22,25 66:15 67:20 68:3 69:10 71:3 72:1 72:14 75:4 86:21
providing 9:5
public 49:9 59:15 60:10
publically 31:14
publication 33:4 80:6
publications 72:19 75:4
public's 87:24
publish 19:10 45:16 49:23
published 12:4 14:13,23 15:10,11 16:24 19:3,8,13 20:7,8,15,17,19 22:25 23:6,9,10 30:12 31:11 33:14 59:16 60:15 70:25 71:15 72:4 75:6 75:10 78:9 80:18 80:19 93:25 97:15 98:2
publishers 75:8
pulled 51:3 58:25

purchased 14:25
purpose 11:3,5,6 59:1
purposes 89:17,18
put 25:11 46:25 60:11 72:15 77:6 93:23,23,24,24 96:7,8,9 97:14,19 98:1
puts 32:24 60:13 80:17
putting 81:4
p.m 100:25

Q

qualification 42:14
qualified 73:12
qualify 70:20
qualifying 42:23,23
quality 77:5
quantities 34:14 98:22
quarterly 20:3
queried 24:23 38:7 38:11,22,25 44:1
query 25:2 39:8,8
question 15:18 17:5 17:15,18,20 18:10 18:18 21:3,4 22:5 22:9 24:2 26:6 30:24 31:1 32:25 35:4,7 42:21 43:1 44:2 45:5 48:12 49:1 51:3,4 53:12 54:19 59:12,14,19 60:2 68:21 69:6 70:5 74:14,16 81:13 89:15,16 92:20,22
questionnaire 6:11
questions 12:10,16 20:25 25:10,11 29:12,13 54:2 58:19 60:24 61:14 73:21 78:17
quick 8:7 31:4
quickly 26:8 35:23 35:24 46:4
quite 4:20 41:18
quote 13:10 25:17 29:17 41:25 64:2 91:9
quoted 61:22

R

R 1:13 101:1
raise 89:16
raised 78:17 85:19
Ralphie 97:10
range 66:10
ranges 36:18
rat 34:16
rate 39:13,14 44:12 44:15 51:19,20
ratios 16:25,25 18:11
read 7:17 40:14 86:13
readers 41:24 51:22 64:13
reading 7:18
real 82:3 85:1
reality 93:12
realize 76:16
really 33:16 65:11 79:5 82:10 87:18 90:22
realm 93:5
realtime 9:5 85:1
reanalysis 87:16
reanalyzed 49:6
reapproved 67:1,1
reason 33:1 43:24 45:1 46:11 85:7
reasonable 21:7 82:22
reasons 88:5 96:2
rebuffed 15:17
recall 13:24 25:6 41:11 58:5 79:16 80:23 83:16
received 31:12 74:3
recipients 43:5
reclassified 47:17 47:21
recommend 65:15
recommendation 55:17
recommended 13:4 19:16 20:11 36:17 93:9
record 34:15 37:4 40:14 42:25 71:4
recorded 1:21 37:24
recording 1:21
recordings 101:7
redesigning 61:11
reduction 61:9
reevaluating 47:24 47:24
reevaluation 48:15
refer 13:11 31:23 53:4
reference 12:11 13:25 18:1 33:9 36:9 38:6,6,7
referenced 38:5
references 14:2
referred 54:20
referring 13:12
reflected 8:18
REGION 1:23
Registered 101:4
registry 16:19 24:9 46:21 60:7 62:23 80:9
regulation 50:6,6
regulatory 61:16 62:16 77:24
reiterates 56:15
related 67:10,15 69:21 80:17 91:1
relates 6:3,15
relating 27:1 30:17 80:19
relationship 18:25
relative 17:1
relevance 36:15
relevant 26:5 30:16 33:6
reliability 12:13 23:25 26:6 77:21 77:21 78:3 89:18 91:3
reliable 23:4 48:13 54:3 56:25 57:11 64:21 88:7 89:9
reliably 12:5
reliance 13:1
relied 65:14 78:4
relies 14:6,8
relitigate 53:14,15
rely 13:7 61:14 77:25 82:11 91:17
relying 56:21 98:25
remain 87:16
remainder 87:11
remaining 22:4,5 23:17
remains 87:12 89:3
remarkable 69:3
remember 47:20,20 69:24 97:9
remind 35:5
reminder 15:12 24:10
Renaissance 2:6
renewal 68:18
repeated 55:25
replicated 56:25
reply 6:21,21
report 4:11 14:1,2 15:23,24 16:4,9 16:13 18:7,23 24:4,6 26:18 27:3 29:4,8 35:17 38:13,16 64:23 66:6 69:15 73:17 74:21 78:13 80:12 80:24 82:2,5,17 82:19,25 83:2,2 83:24 85:9 86:22 92:18 93:24 99:6 99:14
reported 16:7 28:8 28:10,11 54:21,22 59:22 60:9 63:2 63:18 64:3 87:15 92:24 95:6
reporter 7:15 101:5
reporting 1:23 18:11 42:6 43:4,7 95:17
reports 4:4 10:12 13:20 14:12 16:7 16:18 17:11 18:19 56:17,21 57:20 70:3 72:1,25 74:3 76:20 77:5 78:25 83:21 86:10 89:25 90:21 91:17,17
report's 69:16
represents 19:24
request 8:2,3 46:13 86:5 91:15
require 53:14
requirements 42:14
requires 31:20 50:22
research 42:6 43:4 50:12 69:19
researcher 42:2
researchers 15:6 43:13
researching 43:8
reserve 5:20 52:6
resign 79:17
resistance 49:17
resolution 24:24
respect 4:11 45:9 51:11 63:18
respectfully 73:2 86:5
respond 96:16
responded 16:3 17:22 21:8 28:18
responses 25:2
responsible 10:17
rest 54:11 60:15 62:14,14,15
result 31:2 66:16
results 54:21 95:5
retained 71:12,19

retracted 70:24
retrospective 80:1
returned 25:2
returning 69:12
review 37:11 51:24 53:17 68:17 77:19
reviewed 24:22 30:13 44:21 66:1
reviewers 31:10 41:24
reviewing 37:10,13
re-categorized 46:20,21
Ridgeland 2:7
right 5:2,11 6:2 8:5 8:10,11 9:21 12:1 14:18 22:9,9,19 22:20 33:17,22 34:2,6 35:4,8 38:23 40:20 45:16 52:3 55:19 58:24 90:19 96:13,18
ringing 24:13
rise 100:23
rises 30:20
risk 16:24 18:11 26:15 54:15 56:2 56:6,18 57:4,22 58:7,10,17,23 61:8 65:18 76:10
risks 17:1
Road 1:15
Robuck 42:8,19 43:3 49:25 66:19 67:8 68:20 71:17 78:6
Robuck's 43:12
role 12:14
RPR 2:9 101:13
rule 7:9 12:14
ruling 7:11
rulings 9:15
running 60:6

S

S 1:10 3:12
safe 19:17,22 20:10 21:6,7 23:7,10,13 56:20 58:6
safety 54:8,11 55:18 61:12 65:17 67:23 68:4,7 93:20
SALES 1:5
sat 67:8
savvy 8:7
saw 28:19 30:5 37:11 38:6 83:12 95:2,17
saying 25:15 80:12 81:6,25 90:24,24
says 25:18 33:19 38:15 48:3,7 50:1 55:11,23 56:19 74:22 76:13 77:16 78:2 81:18 82:1 84:21 85:9 88:1 92:21,22 93:25,25 97:10,16
schedule 11:13
scheduled 11:13
scheduling 7:5 9:24
Schiodt 19:14
science 18:21 22:21 39:15 44:14 45:8 50:21 61:15 85:2 93:6 94:3
scientific 19:3 23:25 31:13 57:21 61:16,20,25 62:15 63:16 72:12 78:14 79:8 99:2
scientist 42:22 74:4 81:12 82:23
scientists 22:20 42:13 54:18
screen 32:8 35:19
Screens 27:9
scrupulously 68:16
sealed 31:20
second 4:19 12:21 15:4 18:22 22:8 24:1 33:5 34:20 47:25 82:1 87:9
seconds 99:16
section 26:9,19,25 27:2,4,6,8 32:11 33:10 35:20 36:10 38:5 58:13,14 63:24 84:11
sections 26:4 27:15
SEDRAN 1:11
see 22:7 26:20 28:14 30:10 32:10 35:20 37:6 39:16 40:11 45:18 47:2 52:9 55:21 57:7 60:19 72:18 74:7 75:25 76:2 78:10 78:12 80:4,10 82:5,10 83:8 88:19,20 100:21
seeing 46:14
seen 7:21 51:13 62:22 68:22 79:12
selection 6:25
senator 50:11,14
sending 49:5
senior 71:9
sense 78:12
sent 29:5 34:18 45:3,4,6 86:9,17 86:23
sentences 64:7
sentencing 11:13
sepsis 70:9
September 10:23 13:16 52:19
series 16:6,17,19 17:12 18:19 20:2 79:10
serious 35:23
service 1:22
set 4:23 6:4 65:19 66:22,24 100:16 100:18
setting 50:22 57:10 88:25
seven-day 6:21
severe 64:8
shared 9:10
shift 77:13
shock 70:9
shoot 97:11
short 11:9,10 51:17 71:24
shortly 4:5 45:11
show 32:8 35:13 40:7 56:4 64:15 75:2,2 89:24 90:16
showed 21:23 27:21 45:19 47:18 76:8
showing 48:15
shown 44:16
shows 39:6 41:20 56:10 75:16 90:17 90:18
sic 69:2 77:9
side 11:15
sidebar 11:23
signed 34:20 37:8 86:19,19,23
significant 8:20 18:7,12
similar 10:1
simple 37:21
simply 17:11 34:24 41:22
single 13:7,9 15:1 18:1 36:4 41:21 49:12,14 53:23 62:12 68:19 70:19 75:11 89:9,10 96:6 99:20
single-spaced 87:12
sink 25:18
sinks 14:4
sir 7:24
site 29:9,13 30:7 33:7 36:22 38:9 41:6,7 71:13 72:6 76:18 83:3,3,5,6 84:23,23 85:13
sites 24:9,19,23
situation 34:12 57:10 92:12,25
six 26:22 41:10 72:23 78:17
six-years 62:23
skepticism 91:4
skipping 64:6
slash 7:3
slide 21:23 22:3 45:19
sloppy 80:16
small 65:17
smoking 90:15 97:22 99:20
snippets 58:3 59:2
SNOW 2:2,5
somebody 25:9 34:24 36:10 37:23 41:14
sorry 24:15 40:13
sought 76:12 79:3
sound 1:21 101:7
source 77:4
so-called 12:3 78:24
SPEAKER 8:4 24:15 40:18,24 100:17,20
specific 15:13 16:5 18:10 25:24 38:6
specifically 17:13 17:15 18:24 24:3 27:1 28:3 29:18 39:15 53:21 59:13 59:19 64:4 67:18
spectrum 57:18 62:21 63:9 65:21 94:19 95:20
spend 64:19
spent 63:14 65:4 68:10
SPIEGEL 1:14
sponsored 42:9
sponsorship 50:15
spreadsheet 27:25 28:2,23 37:15 46:8 47:1,6,7,8,16 66:15

spreadsheets 45:25 48:15
squarely 61:21 62:4
stand 15:5 19:21,23 20:13 51:16 57:16 72:11 91:10
standard 81:9,14
standing 5:12 62:3
stands 61:20
start 12:9 57:15 58:2
started 41:10 45:22 60:20
startling 57:25
state 6:18 29:11 35:23
statement 19:18 20:16 45:17 50:7 87:25
statements 23:19 59:15
States 1:1,8 14:16 76:23
stating 23:6
statistically 18:7,12
status 1:7 26:14 35:22
steering 67:7,9
STENGEL 1:7
stop 22:1
Story 97:9
straightforward 53:13
Street 1:11,18,24
strenuous 31:5
stretched 6:16
strike 85:18,22,24
struck 91:16 94:5,7 94:7 96:1
struggling 93:13
student 46:12
studied 63:1 76:6
studies 15:11 51:24 74:12 88:12 91:4
study 6:20 7:7 12:4 14:11,15,19,23 15:12 16:23 17:10 18:5 21:15 24:9 24:18,18 32:12 33:7 36:21,22 40:1 41:10 42:12 42:20 43:24 44:1 44:3,4 46:10 50:12,15,17,18,19 50:22 51:2,3,5 52:2 53:16 54:3 54:10,12,14 56:4 59:21 60:9,22 62:5,8,13,18,25 63:2,3,5 66:2,22 67:2,11 68:5,8,13 68:14,22 69:1,3,8 69:23,24,25 70:22 70:23 71:8,10,18 74:11,18 77:15,22 77:25 78:3,7,18 78:21 79:18,25 80:1,2,8,13,20 81:5,24 82:4 84:7 87:8,21 88:13 89:3,17 90:19,20 92:21,22 93:2,6 93:10 95:5 97:14 98:3,24
studying 70:1
study's 40:9
subanalysis 80:7
subject 42:14 68:17 68:18 76:1
submissions 99:12
submit 23:2,24 32:22 42:5 54:3 78:2
submitted 37:8 78:7,8 86:24 97:20
subsequently 73:19
substance 87:2
substantial 32:24 34:13
substituted 89:4
sudden 64:7
suggest 56:22
suggested 47:7 53:16 78:23
suggests 54:14 57:17 64:8
suicide 34:16 37:1 37:23,25 63:4 64:1
Suite 1:11,14,18,24 2:6
summaries 67:20 68:2
supervised 68:16
supervision 76:24
supplement 4:12
supplemental 4:4 10:12 92:18
support 12:6 55:25 65:25
supports 50:6
supposed 81:10 94:1,1
supratherapeutic 56:1
sure 4:20 8:22 9:9 11:21 32:4,19 53:7 84:4
surprise 5:18
surprised 4:21
surprising 64:18
suspect 74:25 75:18
swims 14:4
symptoms 64:5
S-c-h-i-o-d-t 19:14

T

T 3:12 101:1,1
tab 32:2 35:18 39:22 55:10 72:14 79:10 81:16
tabbed 73:9
table 85:4 90:5 97:25
tablets 37:20
take 11:15 21:8 37:16 40:2 53:9 60:16,18 66:14 72:15 81:8
taken 9:6 19:16 28:15 36:6 49:15 52:23 61:8
takes 46:2
talk 10:11 14:18 15:24 27:9 34:7 59:15 63:10,25 65:8,8 75:11 77:13 78:25 79:5 80:21 85:16 91:14
talked 47:11 63:13 80:22 90:12 95:21 98:11,17
talking 63:15 64:19 65:5,23 86:15
talks 55:16 74:2 80:21
Taylor 6:3,7 60:25
technologically 8:7
technology 40:15
telephone 1:7 41:6 41:7
television 72:9
tell 23:12 28:4 99:2 99:3
telling 79:13
tells 44:24 75:17 91:11
term 16:13
terms 4:6 9:13 11:12
test 33:17,19 50:23 74:7,12 90:10,14 92:11
tested 90:7,8
testified 13:18,22 17:4 30:4,14,19 33:23 39:22 40:17 42:11 43:9,19 46:5 51:1,15 58:15 66:13,19 67:17 75:14 87:10 98:18
testify 14:15 20:23
testimony 14:7 17:2 21:2 31:12 35:13 39:5 41:20 43:12 45:17 50:7 51:17 58:14 59:9 94:18
testing 50:23 76:1 89:13 98:19
Texas 31:7
text 81:19
textbook 72:4
thank 7:24,25 10:6 10:7 11:12 12:2 14:21 32:5,6 52:11,12,15 96:11 96:12,20 98:9,9 99:4,5,9 100:8,9 100:20
Thanks 53:11 84:16
theory 13:3,6
therapeutic 28:13 32:19 57:22 61:7 64:9
thin 6:16
thing 17:23 26:18 27:13 57:14 66:18 75:22 86:21 93:11 98:10
things 9:3 16:5,16 52:21 59:15 61:10 62:20 68:25,25 69:25 70:4,4,9,9 70:13,14,14 74:6 74:15
think 4:3 6:1 8:7,17 9:24 19:24 21:7 26:5 28:7 39:6 40:18 48:11 49:5 52:20 58:12 60:16 66:10 69:13 72:8 72:16,18 73:20 79:13 82:6 86:3 90:3,3 93:14 95:23 97:13 99:14
thinking 19:24
third 12:23 15:9 30:25 89:24
thoroughly 86:7
thought 7:9 24:16

83:13,19
thousand 40:3
three 31:15,24 33:8 35:2,7 39:11 44:17 49:8 54:5,9 68:19 69:16,18 70:16 89:23
throws 50:19 52:3
thrust 95:10
thumb 7:15 8:3
time 6:14 10:25 11:4,10,10 20:19 24:20 28:12 31:15 49:17 52:7,10 54:16 63:14 64:19 65:5,24 68:11,19 71:24 78:22 91:20 93:15 96:7
times 37:7 61:23
Tisi 1:17 3:4 11:17 11:18 52:13,14 53:8,12 55:8,9,13 55:15,20,23 58:22 58:25 59:5 66:8 74:2 81:16,20,23 84:1,5,17 86:3 88:21 91:7,8 96:12 97:1 98:1 98:17 99:6,8,10 99:13,18 100:1,13 100:22
today 4:13 7:8,13 7:22 11:11 13:11 15:24 29:7 32:23 32:25 38:20,22 39:1 41:9 44:2,10 44:19 49:9,12 51:16 87:13
today's 4:23 7:16
told 19:3 21:11 23:16 42:19 45:14 49:10,11 64:13 98:4 100:7
topic 82:9
total 36:7 47:25
tough 21:9
Tox 27:9
toxicity 56:22 71:11 74:8,9,23 75:16 99:21 100:6
toxicologists 72:7
toxins 26:22
track 16:5
tracked 26:15,16
tragic 34:12
tragically 34:17
TRANSCRIBER 2:9
transcript 1:7,22 7:13,16 8:2 101:6
transcription 1:22
transcripts 9:5
transferred 8:21
transplants 73:4
treat 63:7,8
treaters 6:10
treating 36:21 38:7
tremendous 71:24
trial 6:4 13:15 17:9 52:17,19 53:23 57:3 61:14 88:1 95:8
trials 57:19
tried 37:21
true 43:6 48:1 49:10 54:17 63:21 91:12 93:1 101:6
truth 68:11 94:8 96:23
try 47:11
trying 7:20 9:18 12:10 62:2,10 63:6,7,8 64:1
turn 14:6,8 17:13 24:1 30:25 65:21 73:22
turned 86:17
two 4:9 6:7 18:16 19:10,15 20:7,18 23:9 27:15,15 31:7,18 35:10 37:8 49:2,7 54:8 56:21 60:23 61:6 61:13 69:22 70:11 71:2 72:7 79:8 80:4,11,22 82:2 84:6,6 87:3,14 88:17 96:16,18 98:22
Tylenol 1:4 32:13 34:14 36:5,24 37:18 38:5,8
types 25:9
typical 36:15
typically 53:3

U

ultimately 53:24 77:9
Um-hmm 99:25
unacceptable 39:14
unbeknownst 82:24
unbiased 74:16
unblinded 41:22
uncertain 22:11
uncertainty 22:22 23:22
underlying 12:13
understand 24:5 26:5 33:20 62:2 72:9,11 74:24
understanding 69:4
understands 71:4
undo 62:10
unfolded 65:22
unfortunate 34:12
unilaterally 42:13 43:15
unintentional 64:3
unique 68:13
United 1:1,8 14:16 76:23
unknown 36:1 39:3 64:23
unquote 13:10
unrelated 98:16
unreliable 12:24 56:17 63:15 65:5 81:7 82:21,22 85:12 90:2,10 94:5 95:16
update 7:4
updated 20:4
up-to-date 4:16
use 11:3 36:25 59:6 59:7 64:9 88:1,11
uses 16:13
usually 41:5
UTSMC30059 46:9
UTSW 24:21,22 31:20
U.S 14:25 50:10,14

V

V 1:17
vacuum 66:23
valid 51:8
validated 92:11 93:5
validity 53:16
various 58:15,16 59:3,9 60:21 68:23 75:4
verified 27:24 29:1
verify 30:6
VERITEXT 1:23
vetted 38:10
Vicodin 36:5
video 5:17 11:3
videotapes 11:6
view 12:5
violation 42:3
virtually 13:18 21:24
visual 11:5,7
vital 25:18
vitamins 26:24
votes 62:7

W

wait 82:1
waive 42:13,14,22
waived 40:11 41:2 41:3,3,11,22 43:16
waiver 41:4,23 42:20,21,24 43:18
waivers 43:9
walk 26:8
Walnut 1:11
want 8:22,22 9:8,8 9:9,22 16:11 19:6 59:14 65:11,21 79:5 83:18 85:20 85:25 87:4 88:10 89:23 96:14 98:5 100:16
wanted 4:19 7:3 16:5 28:13 32:8 46:6 95:22 96:16
wants 8:23 9:11 44:14
warn 6:7
Washington 1:18 6:18 29:11,11
wasn't 37:10 61:25 85:19
watch 72:9
way 13:12 25:16 26:2 51:8 74:19 75:19 85:10 92:17 95:24,24
week 6:17
well-accepted 18:21
went 22:15 24:5 29:12 48:21 49:8 67:22 86:18 95:24
weren't 70:1 90:25
we'll 4:5 11:15,15 27:9 34:7 78:25
we're 5:14 6:9,12 7:23 8:24 11:6 15:24 20:14 24:4 31:23 34:9 52:22 60:20 65:23 94:1 94:1 96:13 98:4
we've 21:15 31:17 35:7 49:6 95:21 96:4,5
widely 72:2
William 71:6
willing 71:22,23

window 89:13 90:4
wish 83:14
withdraw 35:13
withdrawn 19:25 20:16 31:15 33:3 33:15 35:7
withdrew 32:14 33:5 35:6,10
witness 42:9 99:21
witnesses 49:16 58:1,15 59:9 73:13,15
word 87:6
words 23:20 28:22 81:23
work 7:14 37:22 59:20
working 6:5 14:1 54:19,25 55:4,11 56:15,19 62:4 65:14
world 15:6 60:7
worries 8:9
worse 97:8
worth 27:2
wouldn't 42:25
woven 78:25
wrangling 96:7
wrap 45:10 53:22 91:7 95:21,22
write 19:10 20:13 22:9 29:8 31:2 66:17 73:8,10 74:21
writings 23:19
written 20:18 24:20 27:24 28:2 30:10 32:12 33:8 34:15 37:7 44:24 89:17 99:11
wrong 22:19 24:5 62:16 74:5 90:21 95:6
wrote 19:15,20 20:5,9 22:7 25:15 29:4 35:10 36:10 36:23 38:12 50:10 50:14 52:1 60:14 64:23 82:2,7,25 98:1

X

X 3:1,12
X'd 31:18

Y

Y 2:9 101:4,13
Yeah 40:22 41:1
year 6:9 13:17 60:20 96:5
years 19:10,20 20:7 20:18 23:9 31:7 36:1 38:22 59:16 60:16 68:5,14,19 68:24 71:8 93:14
yesterday 4:14 7:2 85:25
York 2:3

Z

Zimmerman 21:19 21:19

0

008 39:21
010 64:25 82:15 88:9,16,17 99:24
026 31:25 32:2
035 33:5
042 35:12,17 46:16 47:2 48:3
051 46:17

1

1 20:11 24:7 72:14 85:4 90:5
1,200 36:10,11 37:14,16,20,22 38:1
1.0 97:17
1.2 36:11
10 30:9 32:19 55:16 56:1 58:8,18,23 59:16 60:5 83:1
10:11 1:6
10:19 11:24
10:21 11:24
10019 2:3
107 92:14
108 92:14
11 53:22 55:3,15 60:3 66:10 83:1
116 46:20 47:18 48:9,9
12 3:4 25:25 82:15 82:19 84:1 88:16 99:24
12.5 88:23
12:23 100:25
12:30 11:14
120 36:14,19
13 19:20 26:9 35:20
1368 27:21
1370 63:24
14 35:18 38:22 73:23,25 87:6
1400 2:6
15 59:16 60:16 73:23,25 90:6 93:14
150 71:10
152 72:21
16 39:13 49:20 51:19 87:15 89:4 89:19 90:7
16th 6:12,23
17 53:22 59:12 87:15,15 89:4,19
1700 2:3
18 26:25 87:16 90:7 90:7
1800 1:24
1801 1:24
1825 1:18
19 12:3 13:23 14:3 14:8 15:16 20:20 22:23 23:3 26:7 27:22 28:3,5,7 29:17,18 30:11,20 31:15 32:2 33:14 35:15 39:11 45:4 51:11 54:10 57:8 62:25 63:12 64:20 65:9 66:4 77:1 82:18 89:5 90:7 94:20,22
19103 1:24
19106 1:12
1997 25:25
1998 19:9,11 22:24 41:11 62:24

2

2 30:10 45:16,18,19 46:7 48:6
2:00 11:14
2:13-md-02436-LS 1:4
20 36:18 68:5,24 71:7
20-year 59:20
20006 1:18
2002 38:11
2003 19:9,12,13,25 22:24 23:6 58:8,9 60:13 62:24
2005 12:5,19,22 13:19 14:2,23 15:4,9,15 17:14 17:19 18:24 19:8 20:8,19 23:4 24:3 27:17 33:25 34:5 38:12 45:22 46:14 47:25 49:4 50:25 65:12
2006 50:11 52:1
2007 20:5 23:10
2009 20:22 23:12 45:14,18,23 47:14 48:1,4,8,20 49:2 99:2
2011 97:14
2013 21:13 23:16
2015 80:3,5
2016 1:5 29:1 65:23 80:5,10 81:17 101:13
202 1:19
21 21:23 30:13 44:12,15 49:20 51:20 82:14 91:9
215 1:12
23rd 6:25
2450 1:14
256 27:19
27 1:5
275 27:19 63:1
28 14:24,25
286 92:21
29 80:10 81:17 101:13
29th 9:25 82:17
299 40:7

3

3 30:12 46:8 58:23 79:10 97:23 98:21
30 29:1 36:18 71:15 99:16
30th 82:8,9
30326 1:15
322 98:20
325 37:18
34 72:22 83:1
35-year-old 34:13 36:23
36 72:22
37 83:1
39158 2:7

4

4 3:2 12:6 13:14 14:5 17:6,21 18:9 19:5,16 20:11 23:6,10 28:9,21 32:20,21 40:3 48:14 56:5,23 57:3,23 58:10 59:24 61:4 76:25 83:11 89:1,6,20 98:19
4-gram 76:7 100:2
404 1:16
41 30:9 87:9 97:24
42 30:9,12
48-page 87:11

5

5 56:11 59:25
50 32:18
500 1:11
500-milligram 37:19
510 1:11
52 3:4
592-1500 1:12

6

6 32:16 59:25 76:6
6-gram 32:24
601 2:7
606-2995 2:4
646 2:4

7

7 83:9 98:21
7.5 56:11 64:10 87:8
700 1:18
702 12:15
777-6690 1:25
783-6400 1:19

8

8 15:1
80 35:25 36:1
832-8000 1:16
86 58:19 59:11
88 72:21
888 1:25

9

9 39:22 88:7,16 100:3,3,5
9th 6:12,21
950 1:15
96 3:4
985-4427 2:7
99 3:4